EXHIBIT 4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

TRAVEL TRANSCRIPT

DePUY MITEK, INC.,
Plaintiffs,

vs.

ARTHREX, INC., a Delaware corporation,
Defendants.

DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Courtyard Marriott, 423 Speen Street, Natick, Massachusetts, on Thursday, 26 January, 2006, commencing at 10:44 a.m.

MR. BONELLA: Answer that yes or no.
A. Yes.
Q. Did the general subject matter concern the process of obtaining a patent for that work?
MR. BONELLA: You can answer that yes or no or to the extent you remember.
A. The process -- clarification: The process of obtaining a patent in general or this patent?
Q. This patent. This patent.
A. No.
Q. And again, I want to make sure that you understand the question that -- when I mean that the steps of applying for a patent and the steps of prosecuting a patent --
A. No.
Q. Didn't get into that.
A. (Nods.)
Q. Was there any other -- in the general subject matter, was there any other general subject matter that you discussed other than your work that you did that led up to the patent?
A. No.
Q. Other than that one meeting that you had with Mr. -- that meeting was with Mr. Bonella?
A. Yes, and one of Mr. Bonella's associates.

Q. All right. Who else was there?
A. It was a woman. I don't remember her name.
Q. Was it Ms. Malinoski?
A. Do you know her first name?
Q. Lynn.
A. Lynn, yes.
Q. Was anyone else there other than the three of you?
A. No.
Q. Other than that meeting, was there -- have you had any discussions with anyone associated with the Johnson & Johnson Company about this litigation?
A. No.
Q. Other than that meeting, have you had any discussions with anyone associated with Johnson & Johnson Company concerning the work you did that led to the Hunter patent?
A. No.
Q. In connection with your preparation for your deposition today, other than -- did you do anything other than review the Hunter patent and the meeting you had with Mr. Bonella yesterday?
A. I did no other activities. Only those two

activities.
Q. In connection with your deposition today or in preparation for your deposition today -- other than logistics -- have you had any discussions with anyone associated with any Johnson & Johnson Company for purposes of preparing for your deposition?
A. No.
Q. While you were -- I want to ask questions about the -- particularly the time period of 1988 to 1992 when you were at Ethicon. Let me ask this first: Once you left Ethicon in '92, did you have any communications with the lawyers who were prosecuting the application that led to the 446 patent, Hunter patent?
MR. BONELLA: You can answer that yes or no.
A. Yes.
Q. Okay. You did. Okay. Were those communications oral or just in writing or both?
A. My recollection were status updates of -- from the attorney --
MR. BONELLA: Again, don't disclose the substance of the communications. That is privileged because it's between an attorney and

you.
THE WITNESS: Okay.
A. So --
MR. BONELLA: The question was --
A. Oral or written? My recollection, were oral; possibility there was e-mail status, but --
Q. Were any of the communications that you recall -- were they substantive about issues involved -- that had arisen during the course of the prosecution, or were they merely just, Here's where things stand?
MR. BONELLA: You can answer that yes or no or -- if it's a yes-or-no question. You can answer it -- were there -- the question is, "Were any of the communications that you recall, were they substantive about issues involved that had arisen during the course of the prosecution or were they merely just Here's where things stand." You can answer that question there were substantive discussions, or they were just merely about where things stand.
THE WITNESS: Can I ask -- can I ask yourself, this -- to me this would be attorney/client discussions.
MR. BONELLA: Right. That's why --

sutures had to offer, and from an alloying viewpoint, it was a place that you could potentially see the most impact in your first set of experiments, so --

Q. Did you have two different classifications for these two different fibers that you were going to be mixing together?

A. Not at that point. At that point we were talking generically about the advantages of making a composite or alloying.

Q. But were you talking about one group would give one property, and one group would give another property?

A. In some instances, yes.

Q. And how would you characterize the two groups?

MR. BONELLA: Object to form.

A. Well, at that stage -- at that stage, is the question?

Q. Well, let's start with that stage.

A. At that stage, again, we were looking -- we were thinking -- we were envisioning something much broader than just, for example, PE -- Teflon, PTFE, and PET, which we were -- maybe I could take a step back. The environment at the time was we --

Ethicon had multiple development programs going, some of which were to make a product that were -- had better properties than silk, and silk has really good handling properties. Some of them had to do with higher strength sutures. Some of them had to do with different biologic profiles in terms of strength retention over time. And the initial discussions were how can we address those types of problems with a combination of fiber types.

So, the initial conversations -- and one of the avenues that came out of that was this maybe opportunity to have a suture that has strength better than silk, but pliability like silk. So, that was one of them.

Q. Okay.

A. And that was one that Al and Art had considered in the past. Again, I'm not clear how far they took that in the past, but they at least considered that. And that was one that we elected to pursue earlier than later, because we had the materials, essentially. We thought it was good opportunity.

Q. So, if I understand your testimony -- at least at the very beginning stage you wanted something that was stronger than silk but handled

as well as silk, is that --

A. That was certainly one of the embodiments we were going after.

Q. As the -- as the project -- as the project progressed and as you applied for a patent, is it correct that you were trying to get something that handled better than a homogenous braid but didn't lose strength -- appreciably lose strength from the conventional homogenous braid?

A. The overall project, yeah, I think that was -- that would be a fair assessment of the objective of the overall project.

Q. All right. And the conventional homogenous braid that you were talking about that you wanted to not lose appreciative strength then was Ethibond, is that correct?

A. Right. Ethibond -- well, Ethibond, you know, had good strength, but maybe not as good handling properties as silk,.

Q. Right.

A. Silk had lower strength, good handle properties, and again, one of the concepts was we -- maybe we could get the best of both.

Q. All right. But as you applied for the 446 patent, was it the object there to have something

that would -- you weren't trying to make something stronger than Ethibond, correct?

MR. BONELLA: Object to form.

A. No, I can't say that we were trying to make anything stronger than Ethibond. We were looking at this as a technology that could improve -- that could offer properties outside of what the current ones -- so, I mean, could be a potential of blending polyester or something else.

Q. I'm talking about the patent now, as you applied for the patent. I mean, if I didn't make that question clear, I apologize. And so, maybe we should go back to Exhibit 10.

Was it an object of Exhibit 10 -- of the patent, as opposed to the work now --

A. Right.

Q. -- was it an object of the patent to try and produce a suture stronger than Ethibond?

A. (Witness reviews document.) I would say since we're clearly looking at aromids, I would say the answer was yes.

Q. And that was by using an aromid?

MR. BONELLA: Object to form.

A. No. That would be one way of doing it.

Q. Is there anything --

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A. We were certainly looking at fiber. We were certainly considering fibers that offer higher tensile strength than -- than strictly PET.
Q. And that was the aromids?
MR. BONELLA: Object to form.
A. That was one of -- that was one example.
Q. Is there anything else?
MR. BONELLA: In the patent?
MR. SABER: Yes, sir.
MR. BONELLA: If you want to read the patent, read the patent. Object to form.
A. Well, the patent describes generic classes of polymers, and the high strength aspect of it has more to do with how those polymers were processed. So, any of those polymers that are listed, you know, could be processed in a high strength form or a medium-strength form or a low-strength form.
Q. When you're saying, "these," which ones are you talking about?
A. I'm referring to the polymers listed in the claims.
Q. All of them?
A. All of those can be processed to get a range of low, medium, or relatively high strength.
Q. All right. Let's look at the

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specification, if we could.
A. Okay.
Q. Could you look at Column 4, please. Yes. The paragraph that starts at Line 33.
A. Yes.
Q. Is that paragraph disclosing the polymers which are to act as strength --
MR. BONELLA: Object --
Q. -- to provide improved strength to the braid?
MR. BONELLA: Object to form.
A. (Witness reviews document.) I'm sorry. Could you repeat the question.
Q. Yeah.
MR. SABER: Could you read it back, please.
(Question read back.)
MR. BONELLA: Object to form.
Q. Let me rephrase that. Does that paragraph provide suggested polymers to provide improved strength to the braid?
MR. BONELLA: Object to form.
A. That paragraph describes two sets of -- that describes "Lubricating yarns in the first set --"

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Q. Right, in the first set.
A. Right.
Q. "-- that are mechanically blended with yarns of the second set, which act to provide improved strength to the heterogeneous braid." Isn't that talking about the second set, providing "improved strength to the heterogeneous braid"?
A. Yeah, within the context of this paragraph. But once again, PET, for example, could be, you know, could be in a -- in a low strength or medium strength or a high strength.
Q. I'm talking about what's being -- what's being explained in this paragraph.
A. Okay.
Q. Is this -- isn't it true that this paragraph is explaining that the -- that the yarns from the second set are there to provide improved strength to the braid?
MR. BONELLA: Object to form.
A. My read of this is that in this particular embodiment, the second set would be offering strength.
Q. And that's the only yarns that are specifically mentioned are PET, nylon, and aromids, is that correct?

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MR. BONELLA: Object to form.
A. Those --
Q. As providing the strength.
A. Those are the only --
MR. BONELLA: Object to form.
A. -- ones mentioned.
Q. In that paragraph?
A. As far -- yes.
Q. Is there any other mention in this patent -- specific mention of any other yarn there to provide strength?
MR. BONELLA: In the patent?
MR. SABER: Yes, sir.
MR. BONELLA: If he needs to read the patent, read the entire patent to answer the question then.
A. Are there any other fibers mentioned --
Q. Any other yarns mentioned to provide strength --
A. I would say.
Q. -- to the --
A. Any of the polymers that we mentioned could be the strength.
Q. Could you tell me where it says that. I want to know exactly what you're relying upon in

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DAY II

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CONTINUED DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Hilton Hotel, 25 Allied Drive, Dedham, Massachusetts, on Friday, 3 February, 2006, commencing at 9:06 a.m.

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embodiments you described to the attorneys during the -- during the period of -- up to the filing of the application?
MR. BONELLA: That's a yes or no. You do recall it or you don't. Don't go into the substance.
A. No.
Q. You don't recall.
A. (Witness nods.)
Q. When did -- when did you first have contact with the patent attorneys -- strike that. Was contact with the patent attorneys the first thing that happened in your involvement that led up to the filing of the application?
A. Yes.
Q. When did that first occur?
A. I have no recollection of the actual date.
Q. Can you give me any approximation? And you can use -- if you want to use the filing date as a reference, go ahead.
A. There's -- I'm sorry. Could you repeat the question.
(Question read back.)
A. I'm sorry. Sometime after March 1990, but I don't have it.

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Q. Can you give me any estimations between March of 1990 and February 19th of 1992 of when your contacts with the attorneys began?
A. I'd just be guessing. No.
Q. Okay. Can you -- can you give me any way of narrowing that time frame down.
MR. BONELLA: Objection. Asked and answered numerous times.
A. Just too many going on. Too long ago.
Q. Okay. You mentioned Mr. Goodwin and Mr. Skula. Could you describe to me, if you can, kind of what your understanding of their respective roles were in the preparation of the application.
A. My understanding was they were J&J patent attorneys assigned to Ethicon that would work with inventors to actually draft patent applications.
Q. Do you have any understanding of the difference in the role between Mr. Goodwin and Mr. Skula?
A. My understanding was Mr. Skula replaced Mr. Goodwin at some time, but I don't -- I thought they had the same role.
Q. Okay. You believe Mr. Skula replaced Mr. Goodwin?
A. I have some recollection of Mr. Goodwin

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moving on to different responsibilities and Mr. Skula picking up on this. But I -- I have to say I had several applications going, and I don't know if I'm remembering this one.
Q. All right. That change in roles, do you know if that was before the application was filed or after?
A. No, I don't.
Q. You just don't recall?
A. I just don't recall.
Q. And I apologize if I asked you, do you recall Mr. Woodrow being involved in the prosecution of the application?
MR. BONELLA: Objection. Asked and answered.
A. No, I do not recall -- I had no direct interactions with Mr. Woodrow, so if he did or didn't, I wouldn't -- I wouldn't be privy to it.
Q. Okay. Do you know who actually drafted the patent application?
THE WITNESS: Is that --
MR. BONELLA: If you know, you can answer yes or no.
A. I would say it was a joint drafting between myself and, my recollection was, Mr.

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Goodwin.
Q. What do you mean by a "joint drafting"?
A. That there would -- there would be -- that Mr. Goodwin took my input, drafted the basic patent, and then would ask me for my input, and it was an iterative process.
Q. Okay. Just to be a bit more specific about that, if I understand your testimony correct, you provided information to Mr. Goodwin, correct?
A. (Nods.) Yes.
Q. You have to verbalize.
A. Yes. Thank you.
Q. And then he took that information and prepared a draft of the application?
A. Correct.
Q. Is that the way it went?
A. Correct.
Q. And then you reviewed the draft?
A. Correct.
Q. And gave comments?
A. Correct.
Q. Or -- okay. And then did you see a second draft?
A. I would -- I definitely recall a second draft.

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Q. And did you give further comments?
A. At that point I can't remember how many iterations, but it was more than one.
Q. Okay. Well, when you -- the "more than one" means at least two?
A. Yeah.
Q. And you recall giving comments on the first draft that you saw, is that correct?
A. Yes.
Q. And do you recall giving comments on any further -- further iterations?
A. I don't recall. I don't recall how many iterations that one went.
Q. I know, but you know there were at least two. And what I'm trying to get is whether you recall giving comments after the first draft.
A. I don't recall.
Q. Okay. Were any of the other named inventors involved in the process of providing information for purposes of the preparation of the application? That you know of.
MR. BONELLA: Object to form.
A. Yeah. They wouldn't have gone directly through me. They would have been through -- directly to the attorney, so I don't have any

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recollection that -- of their input.
Q. Okay.
A. But I may not have had admissibility --
Q. Let me just ask a couple of follow-ups to that.
A. Please.
Q. In any of the meetings that you had with the attorneys, were any of the other inventors present?
MR. BONELLA: Object to form.
Q. And any other named inventors present?
MR. BONELLA: Object to form.
A. I do have a recollection of a meeting with Al.
Q. Al Hunter?
A. Yes.
Q. With the patent attorneys?
A. I do have that recollection. It's been some time ago, but I do have that recollection.
Q. So, at least -- and was that meeting that you recall that Mr. Hunter was present at, was that one of the meetings for the purpose of giving information to the patent attorneys for the preparation of this application that led to the 446 patent?

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A. Yes. And by "meeting," in this case I'm referring to either face-to-face or e-mail correspondence.
Q. Okay. Well, let me follow up on that. With the one with Mr. Hunter, do you just -- did you send -- when you meant e-mail, are you talking about a joint e-mail that --
A. An e-mail stream that people are commenting on.
Q. Right. Was e-mail being used in the '90, '91, '92 time frame?
A. Yeah. We had e-mail in '91, '92.
Q. And that's what you recall? This is some e-mail streams that Mr. Hunter was involved in that led to the preparation of the application that led to the 446 patent?
A. Yeah, I -- I do recall a -- at least one conversation where --
MR. BONELLA: Caution you not -- if it's with an attorney --
THE WITNESS: Yes.
MR. BONELLA: -- don't disclose the substance of the conversation. Describe the circumstances.
A. Yeah, I remember one conversation -- I do

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remember one conversation that involved the attorney and Mr. Hunter and myself.
Q. Was that -- your conversation, was that in person, over the phone, or what?
A. Actually, I do remember one in-person conversation at an early stage of patent drafting.
Q. Between you, Mr. Hunter, and the attorneys?
A. Yes.
Q. And do you recall which attorneys?
A. My recollection would be Mr. Goodwin.
Q. Other than that communication, is there any other involvement of Mr. Hunter that you can recall?
A. I do not recall any other involvement.
Q. How about Mr. Taylor, do you recall any involvement of Mr. Taylor in connection with the preparation of the application that led to the 446 patent?
A. I don't recall any involvement of Mr. Taylor.
Q. How about Mr. Jamiolkowski? Was there -- are you aware of any involvement that Mr. Jamiolkowski had in connection with the preparation of the application that led to the 446 patent?

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A. I do remember conversations with Mr. Jamiolkowski. I do not recall whether Mr. Goodwin was part of those conversations, but I do recall conversations with Mr. Jamiolkowski regarding the 446 patent.

Q. Okay. Let me ask you about any conversations you had with Mr. Jamiolkowski outside the presence of attorneys. Do you recall whether there were any such conversations?

A. There was conversations.

Q. Tell me, when did those occur?

A. Throughout the -- throughout the entire patent drafting process.

Q. What do you recall about any of those conversations?

MR. BONELLA: This is a little tricky. If you're -- if you are -- or Dennis was relaying legal advice that was received from an attorney, that's still attorney/client privileged information. If you're discussing things that did not involve the attorney or were not asked by your attorney to do or to find out, you're discussing technical aspects of the invention, that would probably not be privileged. So, this is a little tricky, but you be careful that you're not

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disclosing any legal advice that was received by either you or Dennis regarding the drafting of the patent application or that had to do with the patent application.

A. Okay. Well, the scope of the conversations that I recall revolve around bioabsorbable constructions of heterogeneous sutures, in particular various copolymer types that would be advantageously blended.

Q. Did you -- do you recall any conversations with Mr. Jamiolkowski about non-absorbable materials to go into the suture?

A. I don't have any recollections of -- Dennis -- Dennis's forte was absorbable polymers.

Q. So, you don't recall any conversations --

A. I don't recall any.

Q. -- with him with respect to non-absorbable materials?

A. No.

Q. Do you -- going back to the drafts, do you know whether any of the other inventors reviewed drafts of the application?

A. I don't know.

MR. BONELLA: Object to form.

Q. Do you recall when you reviewed the first

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draft of the application?

A. Specific month --

Q. Well --

A. -- or do I recall --

Q. In any way you can answer the question. I mean, I'm obviously not asking for the specific date.

A. Yeah.

Q. But any approximations that you can give me.

A. Actually, I don't have the recollection of the first review.

Q. Okay. Do you recall about how much -- how long before the filing -- the February 19, 1992 filing date -- that that review was?

MR. BONELLA: Objection. Calls for speculation.

A. February 19th filing?

MR. BONELLA: Asked and answered.

A. No, I just don't. It's --

Q. You don't know?

A. I -- specific months, years, no.

Q. I mean, can you give me --

A. No.

Q. -- approximation? Was it days before,

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weeks before, months before?

A. It certainly wasn't days before.

Q. Okay. Anything more than that?

A. The process was always longer than, you know, it seemed like it should be. No, I'm sorry. I just don't recollect.

Q. Okay. Do you recall the approximate amount of time it took from when you first met with the attorneys until you received a draft application?

MR. BONELLA: Objection. Asked and answered.

A. No.

Q. Excuse me?

A. No.

Q. Do you recall the amount of time between when you received the first draft and you gave comments to the attorneys?

A. No.

Q. Do you recall the amount of time from the time you gave comments to the attorneys on the first draft to when you received a second draft?

A. No.

Q. I know -- I know you said you recall at least a second draft, correct?

A. Yes. Yes.
Q. All right. Do you recall the period of time from receiving the second draft to any other comments that you gave?
A. No.
Q. Do you recall the amount of time from your receipt of the second draft to the filing of the application?
A. It's just not -- the date -- the timing's just not clear to me. It's just too many patents, too long ago.
Q. So, is your answer you don't know?
A. My answer is, I don't know.
Q. All right. I apologize if I asked this: Do you recall whether you made comments a second time?
A. I don't recall.
Q. Whether you did or you didn't?
A. No.
Q. Going back to the -- the first draft that you received, do you recall the changes that you suggested?
A. That I suggested?
Q. Yes, sir.
MR. BONELLA: That's a yes-or-no answer.

A. No.
Q. You don't know. Did you -- did you make -- did you suggest changes?
A. I have a recollection that there were some edits that I had suggested.
Q. Uh-huh.
A. But certainly not any specifics.
Q. What -- you can't tell me any of the specifics that you suggested?
A. Definitely not.
Q. Looking at Defendant's Exhibit 10, the patent, and looking at the specification of the patent -- do you have the patent in front of you, sir?
A. Yes.
Q. What?
A. I believe so. Is that -- (Witness reviews document.) Yes.
Q. Starting from Column 1 and until -- until the claims in Column 8, do you recall any -- do you recall any differences -- well, strike that. Were there -- there were -- I take it there were differences from the first draft to what you see in the specification of the 446 patent, Column 1 through Column 8 before the claims, is that

correct?
A. (Witness reviews document.) I -- I don't know.
Q. This may be identical to what you saw -- the first draft?
A. It would be unlikely, but it may be.
Q. It's possible?
A. It's possible, but unlikely.
Q. But unlikely.
A. Yeah.
Q. Do you recall any of the changes?
A. I don't.
Q. If there were changes -- in the likely event that there were changes, do you recall any of the changes from the first draft to what appears in the specification of the 446 patent?
MR. BONELLA: That's a yes or no whether you recall or not. Otherwise, it's probably privileged. So, just get a yes or no first.
A. Yes.
Q. You do recall changes. What changes do you recall?
MR. BONELLA: Okay. That's privileged. If that's information that was communicated to your attorney in response to a request for drafting the

application, that's privileged, so I'm instructing you not to answer.
MR. SABER: Mr. Bonella, I didn't ask --
MR. BONELLA: You asked for changes.
MR. SABER: No, I didn't ask what changes he gave. I didn't ask. I just asked what changes from the first thing he saw -- from the first draft to the specification. I just asked what changes.
MR. BONELLA: Your answer necessarily -- the answer to that question necessarily conveys what changes were -- were made. So, it necessarily conveys what was talked about between the attorney and the inventor, so --
MR. SABER: I don't agree with that, but that's why I wanted to make that clarification to see if you'll let him answer the question.
MR. BONELLA: I think -- I don't understand the difference, because it necessarily asked him what changes he recalls from the first draft to this.
MR. SABER: To what's in the spec, right.
MR. BONELLA: Right. So, that necessarily -- necessarily tells -- the answer to that question necessarily tells whether the -- what the changes were, either by the attorney or by the inventor

going back and forth. And that's privileged information. I instruct him not to answer.

MR. SABER: I disagree with you, but --

Q. Will you answer the question?

MR. BONELLA: I instruct you not to answer the question.

A. I'll accept my -- I'll accept Mr. Bonella's recommendation.

Q. Okay. Looking at the specification of the 446 patent, do you recall in what areas of the -- in what areas of the specification there were changes compared to the first draft that you saw which asked --

A. You're asking --

MR. BONELLA: The whole patent, and you can answer that yes, whether you recall. That's yes or no.

Q. Let me try to ask it --

MR. BONELLA: It's a yes or no.

Q. -- in component parts. You see, first it says on Column 1, "Background of the Invention." Do you recall whether there were any changes from the first draft to the -- what we see in the specification to the background of the invention?

MR. BONELLA: That's yes or no you recall.

A. No.

Q. No, you don't recall?

A. I don't recall if there were any changes to that.

Q. How about to the summary of the invention, do you recall whether there were any changes from the first draft to what's in the specification?

MR. BONELLA: Again, yes or no.

MR. SABER: Or I don't recall.

MR. BONELLA: Or I don't recall. Right. Thank you.

MR. SABER: Or I don't know.

MR. BONELLA: Right.

A. No, I don't recall.

Q. You don't know if there were changes to that section.

A. (Witness nods.)

Q. How about the brief description of the drawings, do you know if there were any changes in that section?

A. Do not recall.

Q. How about in the detailed description of the invention, do you know whether there were any changes in that section? And again, this is from the first draft to what appears in Defendant's Exhibit 10.

A. I do recall.

MR. BONELLA: Yes or no.

A. Yes.

Q. You do recall there were changes in the section of the detailed description of the invention.

MR. BONELLA: Yes or no.

A. Yes.

Q. Okay. What changes do you recall?

MR. BONELLA: And I'll instruct you not to answer. It's attorney/client privilege.

Q. Will you answer the question?

A. No.

Q. Let me ask about the examples. It starts on Page 6. Do you recall -- and that would go -- examples goes from there until the claims.

A. (Witness nods.)

Q. Do you recall whether there were any changes in that section from the first draft to what appears in Defendant's Exhibit 10?

MR. BONELLA: Again, it's yes, no, I don't know, I don't recall.

A. Yes, I do remember there were changes.

Q. Okay. What changes do you recall?

MR. BONELLA: I instruct you not to answer. That's attorney/client privilege.

A. I accept the recommendation.

Q. Will you answer the question?

A. No.

MR. SABER: Could you mark this.

(DMI095016 marked Exhibit 79.)

(DMI095017 marked Exhibit 80.)

Q. Doctor Steckel, let me show you what's been marked as Defendant's Exhibits 79 and 80 and ask you if you've seen these exhibits before or seen these documents before?

A. 79 and 80?

Q. Yes, sir.

A. (Witness reviews document.) Yes. I do remember these.

Q. Okay. Looking at Exhibit 79, this is dated February 3, 1992, is that correct?

A. Right. Right.

Q. In the second paragraph it says that, "Mark received comments from the remaining coinventors. I understand that Mark received comments from the remaining coinventors." Do you see that?

A. I do see that.

Q. Is that understanding that you're the Mark that's being referred to there?
A. Yes.
Q. Did you, in fact, receive comments from the remaining coinventors?
A. It would have been practice for me to distribute the draft to all the inventors for comments. They may or may not have made any.
Q. But is it your recollection that you -- you got the drafts and you were the one responsible for distributing the draft to the coinventors?
A. That's actually not my recollection, but it would have been my practice to circulate it to all the inventors.
Q. Well, what is your -- what is your recollection in this instance with respect to this application?
A. I have no recollection.
Q. Do you recall whether you received comments from the remaining coinventors?
A. No, I do not.
Q. Okay. Do you see in the next paragraph it refers to two voice mail messages for Mark during the first week of January?
A. Yes.

Q. This is from Mr. Goodwin, this memo, correct?
A. Yes. Yes.
Q. Do you recall receiving voice messages from Mr. Goodwin during the first week of January 1992?
A. No, I do not.
Q. Do you have any reason to doubt the accuracy of what's stated here?
A. No, I do not.
Q. Did you -- do you recall responding to Mr. Goodwin between the first week in January and February 3 of 1992? Strike that. Do you recall communicating with Mr. Goodwin between the first week in January and February 3 of 1992?
A. No, I do not recall.
Q. Do you have any reason to doubt that you did not communicate with him during that time period?
A. Between the 1st week of January and February 3rd? No, I have no reason to doubt Mr. Goodwin's statements here.
Q. Okay. Now, in the -- in the second paragraph it says, "I sent a substantially-completed draft, including examples

and drawings, to Mark Steckel for review and comment." Do you see that?
A. Yes.
Q. Do you recall when you received -- do you recall that you received a draft that's being referred to in this exhibit? Strike that. Do you recall receiving the draft that's being referred to in this exhibit?
A. After reading this document, I do recall.
Q. Okay. Do you know how long you had the draft?
A. No.
Q. From reading this document, is it a fair statement that you had it -- do you know whether you had it by the first week in January?
A. I would say I had it by the first week of January.
Q. And when did you respond to Mr. Goodwin with -- in connection with that draft that you had?
A. I don't know.
Q. All right. It wasn't before February 3, 2002, was it?
A. It would -- I would -- it would appear not from this, but I don't know.
MR. BONELLA: Make sure you get the

question right. The question was, was it before February 3rd, 2002? That's the question.
THE WITNESS: Oh, 2002.
MR. SABER: Oh. I'm sorry. 1992. Thank you, Mr. Bonella.
A. I have a recollection of this being in process when Matt wrote this, but I -- I don't know if it was before or after.
Q. All right. Okay. Let's look at Defendant's Exhibit 80, if we could.
A. 80, yes.
Q. Do you recall that one?
A. Yes.
Q. That's from Barbara Schwartz. She was your supervisor?
A. Yes.
Q. To you?
A. Yes.
Q. And is that sending along the attached memo? Do you have an understanding that the attached memo is referring to Defendant's Exhibit 79?
A. Yes.
Q. And this memo asks you to respond to Matt Goodwin's request?

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A. Yes.
Q. Do you have any recollection whether you had already responded to Matt Goodwin's request prior to receiving this February 10, 1992 memo?
A. I have a recollection of responding right after this February 3rd --
Q. This February 3rd or the February 10th?
A. The February 3rd.
Q. Well, when did you receive the February 3rd memo?
A. I don't know.
Q. You're not an addressee on the February 3rd memo, right?
A. No, but I remember hearing about it.
Q. Well, the February 10 memo attaches the February 3rd memo, correct?
A. Yeah, but I remember hearing about it even before.
Q. Okay. Do you know whether you responded --
A. Could I state that I had already moved from New Jersey to Ohio at this point?
Q. Okay. Sure.
A. So, I was -- I remember -- I remember this memo, and I remember --

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Q. "This memo" being which one?
A. Matt Goodwin's memo.
Q. Right.
A. And I remember someone calling me and saying, Matt wrote a memo to your old boss, Barbara Schwartz, that expressed some frustration.
Q. Right. And the frustration being that he hadn't heard back from you.
A. Right. During my move, 'cause I was moving literally in January of '92.
Q. All right. Do you recall whether you responded to -- was it -- hearing about the February 3 memo -- the February 3, 1992 memo that caused you to respond to Mr. Goodwin?
A. Yes.
Q. And you're not sure whether you actually heard about the memo before you got -- before you actually got it in connection with Defendant's Exhibit 80 on February -- on a document dated February 10?
MR. BONELLA: Object to form. Misstates the record.
A. I have -- I have a recollection of hearing about this memo before -- before the follow-up memo.

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Q. And just so you're -- so the testimony is clear, do you recall when you responded to Mr. Goodwin -- to Mr. Goodwin's February 3 memo?
A. No. I'm sorry. I do not remember the date I responded.
Q. And you don't recall whether it was before or after receiving the February 10 memo?
A. No, I do not.
Q. Let's turn to Defendant's Exhibit 10, the 446 patent if we could, sir. And if you could turn to Column 1, which is on -- well, Column 1. And the first paragraph under "Background" says, "This invention relates to braided multifilaments and especially to sterilized braided multifilaments suitably adapted to use as surgical sutures or ligatures." Do you see that?
A. Yes.
Q. What did you mean by that paragraph?
A. I don't know how else to say it.
Q. Why were --
A. Applies to surgical sutures.
Q. Excuse me?
A. It applies to sterile surgical sutures or ligatures.
Q. What's the difference between a surgical

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suture and a ligature?
MR. BONELLA: Object to form. Calls for expert testimony.
A. My understanding there's not a major difference. It's more how they're used than the actual product.
Q. Why were you including both surgical sutures and ligatures in this paragraph?
MR. BONELLA: Object to form. Assumes facts not in evidence.
A. Ethicon's business was in sutures and ligatures.
Q. Do you think that this is an accurate statement of what the invention -- your invention relates to?
MR. BONELLA: Object to form.
Q. This paragraph.
MR. BONELLA: Object to form.
A. Yes.
Q. Could the braid that the -- the braided multifilaments that are the subject of this patent application -- this patent, could they be adapted for use as either sutures or ligatures?
A. Yes.
Q. And why is that?

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Q. Is that referring to obtaining braid properties for any reason other than the mechanical interlocking or weaving of the individual yarns?

A. (Witness reviews document.) Correct. There has to be some mechanical interlocking.

Q. Is there anything else that's referred to in that sentence, other than the mechanical --

A. No. No, not that I --

Q. -- mechanical interlocking or weaving of the individual yarns?

A. Not that I can interpret from this.

MR. SABER: Okay. Why don't we take a break.

(Recess was taken.)

Q. Doctor Steckel, could you turn to Column 6 of the patent. I want to ask you about the paragraph that begins on Line 5 that goes through Line -- about 17. Specifically, I want to ask you about the question about two-thirds -- the sentence about two-thirds of the way down: "However if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated, saving expense as well as avoiding the associated braid stiffening." If you need to read

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the whole paragraph to answer my question, go ahead. My question is, what's your understanding of that sentence?

A. (Witness reviews document.) Okay. What's my understanding of the last sentence of that paragraph?

Q. Yes, sir.

A. (Witness reviews document.) That this was one potential feature of the heterogeneous braid was that it may or may not need a coating.

Q. If you -- what does it mean that if you -- why could conventional coating be eliminated if a significant "-- if the braid is engineered to possess a significant fraction of the lubricious yarn system"?

A. Why is that the case?

Q. Yes, sir.

A. My understanding is one of the reasons braids are coated is to add lubricity for the knot tie-down, which may be achieved in the right heterogeneous braid system.

Q. I'm just trying to understand your -- your testimony. When you say the right type of heterogeneous system, what are you referring to?

A. As we state, one in which there is a

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significant fraction of the lubricious yarn.

Q. In that circumstance, is this explaining that you'd get the same benefits as you'd get from coating?

MR. BONELLA: Object to form.

A. Would you get the same benefits? I would say you would get some of the same benefits.

Q. Enough of the same benefits that you don't need to have a coating?

A. I don't know if you wouldn't need any coating.

Q. I'm sorry?

A. I don't know if -- I don't know if -- if you wouldn't need any coating.

Q. What does it mean when it says that the conventional coating may be eliminated?

A. Okay. It may be eliminated, so certain embodiments of the heterogeneous braid may give the same performance as a nonheterogeneous braid with a coating.

Q. Okay.

A. In those embodiments, you may be able to get by with no coating.

Q. Now, up further in the paragraph -- up earlier in the paragraph where it says, "If

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desired, the surface of the heterogeneous multifilament braid can be coated --"

A. Yes.

Q. Excuse me "-- to further improve handle ability, knot tie-down performance of the braid."

A. Yes.

Q. When you use the words -- what's your understanding of the words "if desired"? Is it your understanding that means that you can or cannot add coating? You may or may not add coating?

A. You may or may not. That's my understanding.

Q. Coating is -- is optional. Is that -- well, strike that. Is it -- is it your understanding that this sentence means that if you do add coating, it would further improve the handle ability and knot tie-down performance of the braid?

MR. BONELLA: Object to form.

A. The coating's -- the reason why people coat sutures is to improve handle ability and knot tie-down.

Q. Do you know why the word "further" is used in that sentence?

A. I think it is stating that you could get

EXHIBIT 5

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

Declaration of Dr. Matthew Hermes

I submit this declaration in support of DePuy Mitek's Memorandum in Opposition to Arthrex's Motion for Summary Judgment.[1]

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture

[1] I noticed a few citation errors in my previous declaration submitted in support of DePuy Mitek's Claim Interpretation of the Hunter Patent. The citations in ¶8 should be (Tab C) and (Tab C and D), respectively. The citations in ¶¶9 and 12 should be (Tab B). The first citation in ¶11 should be (Tab B).

products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post treatment, stretching, annealing, coating, packaging design, sterilization, testing, assisting with obtaining 510(k) approval, and quality control.

2. In 1996, I authored the book "Enough for One Lifetime," the biography of Wallace Carothers, the inventor of Nylon. While writing this book from 1989-1996, I researched and studied the origins of synthetic fiber science including the history and development of nylon and polyester.

3. Before I worked at U.S. Surgical Corporation, I was a Research Director at Virginia Chemicals, at Celanese Co. from 1979-1983. Prior to being a Research Director, I was a Research Chemist, Supervisor, at E. I. DuPont from 1959-1979. At DuPont, I work with triaxial support systems and supervised a group that worked on elastomer coated fabrics.

4. From 1992-1994, I was an Adjunct Professor of Chemistry at the University of Wyoming. From 1995-1997, I was a Consultant at Colorado Advanced Technology Institute. In 2001 and 2006, I received two Small Business grants from the NIH for the development of unique all plastic manual wheelchairs and worked with Turbo Wheelchair company to develop, manufacture, and sell these unique devices.

B. Education

5. I have a Bachelor of Science in Chemistry from St. John's University, Brooklyn, NY, 1955. I have a Ph.D. in Chemistry from the University of Maryland, 1959. My mentor was Professor William Bailey who developed one of the earliest polymer science research groups in the country. My doctoral thesis related to polymers made using the Diels-Alder reaction. I also have a Masters of Arts in Liberal Studies from Wesleyan University, 1992.

6. A copy of my CV is attached under Ex. 1. A list of my publications and patents are set forth in my CV.

7. It is my understanding that a patent claim is invalid if it is not novel (which I understand is referred to as being "anticipated"), if a single prior art reference teaches, expressly or inherently (necessarily present), all of the claim limitations arranged in the same manner as the claim and enables one of ordinary skill in the art to make and use the invention. I understand that the test for lack of novelty is generally a two-part test. First, the meaning and scope of the claims are determined by the Court. Second, once the claim scope has been determined or construed, the next step in assessing a patent claim's validity is deciding whether one piece of prior art describes all of the claim limitations arranged as claimed. Because the Court has not yet construed the claims of U.S. Patent No. 5,134,446, I have been asked to assume a certain claim construction.

8. It is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not anticipated by U.S. Patent No. 5,318,575[2] ("Chesterfield") because the 575 patent does not teach, either expressly or inherently, all the claimed limitations of these claims.

II. Claims 1, 2, 8, 9, and 12 of The 446 Patent Are Not Anticipated By Chesterfield

A. Legal Framework For My Opinion of No Anticipation

9. The patent laws form the legal framework for my opinions. My understanding of the U.S. Patent Laws is as follows. I understand that the patent statute states that patents are presumed valid. 35 U.S.C. §282. I further understand that each patent claim is presumed valid, and therefore an invalidity analysis must be done on a claim-by-claim basis. I understand that

[2] I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that Chesterfield may not be prior art. For purposes of this report, I have been asked to assume that Chesterfield qualifies as prior art.

because of this presumption, Arthrex or Pearsalls must put forth "clear and convincing" evidence of invalidity to overcome this presumption of validity. It is my understanding that this a higher burden of proof than a preponderance of the evidence standard, but less than a reasonable doubt standard.

10. It is my understanding that a patent claim is invalid if it is not novel (which I understand is referred to as being "anticipated"), if a single prior art reference teaches, expressly or inherently (necessarily present), all of the claim limitations arranged in the same manner as the claim and enables one of ordinary skill in the art to make and use the invention. I understand that the test for lack of novelty is generally a two-part test. First, the meaning and scope of the claims are determined by the Court. Second, once the claim scope has been determined or construed, the next step in assessing a patent claim's validity is deciding whether one piece of prior art describes all of the claim limitations arranged as claimed. Because the Court has not yet construed the claims of U.S. Patent No. 5,134,446, I have been asked to assume a certain claim construction.

11. It is my opinion that claims 1, 2, 8, 9, and 12 of the 446 Patent are not anticipated by U.S. Patent No. 5,318,575[3] ("Chesterfield or 575 patent") because the 575 patent does not teach, either expressly or inherently, all the claimed limitations of these claims.

12. Arthrex asserts that Chesterfield "discloses every limitation of the asserted claims." I disagree. The 575 patent does not disclose many limitations of claims 1, 2, 8, 9, and 12 of the 446 Patent.

[3] I understand that there are legal requirements for whether a document qualifies as prior art. I also understand that Chesterfield may not be prior art. For purposes of this report, I have been asked to assume that Chesterfield qualifies as prior art.

13. The 575 patent does not disclose to one of ordinary skill in the art a heterogeneous braid of the claimed yarns from the first-fiber forming materials with the second fiber-forming materials in direct intertwining contact. Further, the 575 patent does not teach a suture having a braid of PE (including UHMW PE) with PET, Nylon, or aramid. I understand that in order for the 575 patent to anticipate the 446 patent claims, it must disclose every limitation of the 446 Patent claims (expressly or inherently) arranged in the same way as claimed in the 446 Patent claims. Because the 575 patent does not teach all of the limitations of the claimed invention arranged in the same way, it is my opinion that there is no anticipation.

14. In general, Arthrex picks and chooses different teachings of the 575 patent and combines them in a way that is not described in the 575 patent and then concludes that the 575 patent teaches the claimed invention. Basically, Arthrex forms the claimed invention by selecting teachings about a sternum closure device in the 575 patent and combining them with select teachings about a suture repair device in the 575 patent. But I disagree with Arthrex's analysis because the 575 patent does not expressly or inherently describe the claimed invention. I address some of Arthrex's specific points below.

15. Arthrex cites to column 3, lines 61-67, of Chesterfield as disclosing nylon or PET. I disagree. This citation does not refer to nylon or PET. In fact, column 3, lines 61-67, specifies that the material 20 is a "bioabsorbable polymeric material such as . . . polyester" (Ex. 2 at 3:63-67). Neither nylon nor PET are bioabsorable polyesters; they are non-absorbable materials. Thus, column 3, lines 61-67 is not a disclosure of either PET or nylon. Column2, line 62 of the 575 patent describes a sternum closure device, not a suture.

16. Arthrex also cites to column, 3, lines 61-67, of Chesterfield as disclosing nylon or PET braided with UHMW PE in a suture. But I disagree. The 575 patent at column, 3, lines 61-67,

describes that fibers 20 are used in the outer structure in the sternum closure ribbon 10, not a suture. Thus, this citation to col. 3, lines 61-67 does not teach nylon or PET braided in a suture, much less braided in direct intertwining contact with UHMW PE.

17. Arthrex cites the filler yarns 20 of the sternum closure device as being braided with the UHMW PE in the spiroid braid of Fig. 7. But the filler yarns 20 are from a sternum closure device (Figs. 2 and 4) and the UHMW PE (to which he cites) is from a spiroid braid (Fig. 7). Thus, they are not braided in direct intertwining contact as required by the 446 patent claims.

18. Further, Chesterfield does not teach a heterogeneous braid for the braided fibers 20 in the sternum closure device 10 (below). Rather, Chesterfield teaches that the braided fibers 20 are in a homogeneous woven structure (Ex. 2 at 3:61-4:1, 4:39-47). Therefore, his citation to Chesterfield's sternum closure device does not disclose nylon, aramid, or PET braided in direct intertwining contact with PE in a suture, as claimed in the 446 Patent.

19. Again, Arthrex piecemeals two materials from two different structures to describe the heterogeneous braided suture as claimed in the 446 Patent. Specifically, Arthrex takes the UHMW PE from the core of the hollow braid of Figs. 8 and 9 and matches it with either the (1) bioabsorbable polyester of the sternum closure device or (2) the material of the spiroid braid of Fig. 7. This picking and choosing of two different materials from two different structures does not teach a single suture construction having the claimed first and second fiber forming materials braided in direct intertwining contact as claimed in the 446 Patent.

20. Arthrex also cites to column 7, lines 43, 59-60, as disclosing a heterogeneous braid with direct intertwining contact where one of the yarns is PE. But column 7, lines 59-60 of Chesterfield only describes PE in the core. The PE referred to in column 7, lines 59-60, is not in the sheath, is not described as braided with another material, is not described as braided with the

claimed second fiber-forming materials (nylon, aramid, or PET), and is not described as braided in direct intertwining contact with the claimed second fiber-forming materials. Also, column 7, lines 26 and 38 of the 575 patent describe a product with 100% Spectra sheath.

21. Arthrex also cites to claims 11 and 12 of the 575 patent as disclosing nylon and polyester respectively braided in direct intertwining contact with UHMW PE in a heterogeneous suture braid as claimed in the 446 patent. I disagree. Claims 11 and 12 of the 575 patent refer to second non-absorbable fibers as being formed from either nylon or polyester. But claims 11 and 12 of Chesterfield do not specify how the second fibers are braided with the claimed first fibers. For example, Chesterfield claims 11 and 12 do not recite that the first and second fibers are braided in direct intertwining contact, as opposed to a core-sheath arrangement (like that described in Chesterfield Figs. 8, reproduced below, and 9), with the first fiber materials only in the core and the second fiber materials only in the sheath.

22. Further, claims 11 and 12 recite a "method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue..." (Ex. 2 at 8:29-38; 60-64). It is my opinion that this refers to a method of using the sternum closure device, not a suture, because a sternum closure goes "about" the margins of tissue (Ex. 2 at Fig. 1) while a suture goes through tissue. Thus, claims 11 and 12 do not refer to a suture and therefore cannot teach all the limitations of the claims of the 446 Patent.

23. Chesterfield at column 4, lines 9-23 does not disclose the second fiber forming materials (PET, nylon, or aramid) braided in direct intertwining contact with the first-fiber forming materials. That portion of Chesterfield does not explicitly mention nylon, aramid, or PET. Although, that citation does state that "[a]ny number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated"

(Ex. 2 at 4:20-24), it does not disclose how these materials are selected or arranged, such that a person of ordinary skill in the art would understand that nylon, aramid, or PET are necessarily disclosed and arranged as claimed in the 446 patent. For example, it does not disclose PET, Nylon, or aramid braided in direct intertwining contact with UHMW PE, as claimed in the 446 Patent.

24. I understand that for any claimed limitation to be inherently disclosed, it must necessarily be disclosed. I see no reason why PET, nylon, or aramid is necessarily disclosed as being braided with UHMW PE in direct intertwining contact in a suture as claimed in the 446 Patent based on Arthrex's citation to column 4 of the 575 patent. For example, Arthrex provides no explanation as to why one of ordinary skill in the art finds that this statement discloses selecting either PET, nylon, or aramid from the universe of possible yarns. Nor does he provide an explanation of why only one yarn would be picked to be braided with PE in direct intertwining contact when the 575 patent refers to "any combination" of the universe of yarns and does not specify any particular braiding arrangement.

25. I note that when Arthrex was prosecuting an application, which ultimately issued as the 234 patent, Arthrex represented to the Patent & Trademark Office that Chesterfield "does not disclose an example of a braided sheath that includes a blend of both UHMWPE and polyester" (Ex. 3 at DMI041091).

26. Thus, Arthrex's patent counsel agreed with me when it was prosecuting its own patent application.

27. Also, claim 9 of the 446 patent is not anticipated by Chesterfield for the additional reason that Chesterfield does not describe the limitation of claim 9 that the "volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent."

28. Arthrex argues that Chesterfield "discloses all of the subject matter of claim 9." I disagree. It is my opinion that Chesterfield does not disclose all of the limitations of claim 9, arranged as claimed. As described in my previous report with reference to claim 1 of the 446 patent, Chesterfield does not disclose many of the limitations of claim 1, which are also limitations of claim 9.

29. I also disagree with Arthrex's assertion that Chesterfield discloses the limitation that "the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (Ex. 4 at 10:9-11) in column 4, lines 8-24, and Figure 6 of the 575 patent. Figure 6 of the 575 patent is entirely silent regarding the volumetric ratio of any sheath and core materials. I also note that Figure 6 is a spiroid braid that does not disclose a core. Also, column 4, lines 8-24, of the 575 patent does not discuss any volume fractions of materials, much less a volume fraction of PE in the sheath and core relative to the remainder of the suture. Thus, because Chesterfield does not disclose a suture having all of the limitations of claim 9, arranged as claimed, it is my opinion that Chesterfield does not anticipate claim 9 of the 446 patent.

30. As I have opined previously with respect to U.S. Patent No. 4,610,688, fibers which are just straight fibers around which other fibers are braided and not in direct intertwining contact. The 688 patent teaches a ligament prosthesis, not a suture (Ex. 5 at 2:14). Element 9 in the 688 patent is a straight fiber, while the elements 11 and 13 are helically wound around element 9 (Ex. 5 at Fig. 1 and 2; 3:65-4:14). Thus, element 9 is not mechanically interlocked with either element 11 or 13 and is not braided with either element 11 nor 13 "in direct intertwining contact," as claimed in the 446 Patent. For example, in a direct intertwining braided construction, one set of yarns is interlocked with the other, so that they are held within the braid

by the other set of yarns (*see* Ex. 4 at 5:18-26). In contrast, in the 688 patent, fibers 9 are not interlocked with fibers 11 or 13.

III. The Inventors Reduced the Claimed Invention to Practice

31. Generally, I understand that in order for a claimed invention to be actually reduced to practice, the invention must have been made and evaluated so that the inventors knew that it would work for its intended purpose.

32. I have reviewed Dr. Steckel's deposition transcript, Dr. Jamiolkowski's testimony, and Dr. Steckel's lab notebooks. It is my opinion that the inventors had made and tested a braided suture that was suitable for its intended purpose and had proved the concept of the invention at least as early as February 1989 and December 1989. I understand from Dr. Steckel's testimony that he referred to some of the work that led to the 446 patent as "Composite Braid Evaluation" or "CBE" (Ex. 6 at 135:1-21).

33. Dr. Steckel's notebook describes conception of the claimed invention at least as early as June 6, 1988 (Ex. 7 at DMI002617). Dr. Steckel describes his idea as "[a] preliminary evaluation of composite braids, i.e., braided sutures constructed of two or more fiber types designed to realize the beneficial properties of each polymer" (*id.*). He further states that the composite sutures to be evaluated included carrier blended "PET/PTFE" and "PET/PP" yarns in which blending occurs when two different yarns reside on different carriers during the braiding operation. (*Id.*). Thus, at least as early as June 6, 1988, he had described the broad concept of a heterogeneous braided suture with two yarns in direct intertwining contact and provided two specific examples of braiding PET/PTFE and PET/PP (*see also* Ex. 8 at 99:7-25; 100:20-23; 102:10-17; 127:12-21; Ex. 6 at 159:6-23; 160:17-22; 161:4- 10).

34. Dr. Steckel's notebook and testimony confirm that he built a suture braid as claimed in the 446 patent at least as early as June 6, 1988 (Ex. 7 at DMI002618; Ex. 8 at 127:12-128:21; Ex.

6 at 218:21-25). For example, Dr. Steckel built the CBE-15 prototype on June 6, 1988 with a carrier braider ("CB") (Ex. 7 at DMI002618). The CBE-15 braid was made from braid of 51% PET and 49% PTFE by volume (*id*.). The yarns used to construct the CBE-15 braid are specified on page DMI002619 of Dr. Steckel's notebook (*id*. at DMI002619). In June 1988, Dr. Steckel performed basic suture testing on CBE-15 including straight tensile and knot tensile testing (Ex. 6 at 219-220). Thus, at least as early as June 6, 1988, Dr. Steckel had conceived of the idea of braiding two materials, of the type claimed in the 446 patent, in direct intertwining contact to form a suture and had made a suture having these characteristics.

35. Dr. Steckel's notebook describes prototypes that he had constructed and tested as least as early as February 2, 1989 (Ex. 7 at DMI002635-38: Ex. 6 at 220:1-221:2). He had constructed PET/PTFE carrier braided sutures designated as CBE-15 having PET and PTFE yarns which were carrier braided in direct intertwining contact (Ex. 7 at DMI002635-36; Ex. 6 at 222:7-223:20). Dr. Steckel testified that "full characterization" of the braids had been completed at least as early as February 1989 (Ex. 6 at 218:12-219:6). His notebook describes various testing that he performed on the braided sutures (Ex. 7 at DMI002637; Ex. 6 at 222:2-11).

36. Dr. Steckel had constructed and evaluated a suture that is within the scope of claims 1, 8, and 9 of the 446 patent at least as early as February 1989 (except it was not sterile). He had built a "heterogeneous suture" of PTFE and PET yarns. The PTFE and PET yarns were "continuous and discrete yarns" as claimed in the 446 patent (Ex. 4 at 8:65). They were also in "direct intertwining contact" because they were carrier braided (*id*. at 8:67). The PTFE yarns were a "plurality of filaments of a first fiber-forming material," and the PET yarns were "a plurality of filaments of a second fiber- forming material" as claimed (*id*. at 9:1-8). The volume fraction of the PTFE, the lubricating yarn, was 49% by volume (Ex. 7 at DMI002636). Further, Dr. Steckel

had tested and evaluated the sutures. Therefore, he had reduced the sutures of claims 1, 8, and 9 to practice at least as early as February 1989.

37. I also note that Dr. Steckel built and tested prototypes in December 1989 (Ex. 7 at DMI002665-67). These prototypes were carrier blends of PTFE and PET yarns that were braided in direct intertwining contact (*id*. at DMI002665). The specific braiding sequence is shown in Dr. Steckel's notebook (*id*.). Similar to the prior PTFE/PET braids, these braids are also within the scope of claims 1, 8 and 9 of the 446 patent. Dr. Steckel evaluated the December 1989 prototypes and noted that the prototypes offered "exceptional handling properties for a braided suture" (*id*.). He also found that these prototypes "ranked better" in "handling properties" and knot-tie down relative to silk and Ethibond (*id*. at DMI002666; Ex. 6 at 235:24-236:10). As he explained, the bending modulus of the composite PTFE/PET suture braid was lower than silk and Ethibond (Ex. 7 at DMI002666-67). This means that the PTFE/PET braid was more flexible than silk and Ethibond. Dr. Steckel further noted that the intrinsic tensile and knot strength of the composite braid were 87 ksi. and 48 ksi. respectively. Based on Dr. Steckel's construction and evaluations, it is my opinion that Dr. Steckel had reduced to practice the claimed invention at least as early December 1989.

38. Arthrex's argues that the inventors of the 446 patent did not actually reduce the invention to practice in February 1989 or prior to the February 19, 1992 filing date of the application. I disagree. The inventors had constructed a suture that they knew would work for its intended purpose.

39. Arthrex argues that the inventors never actually reduced the claimed invention to practice because they did not construct a "sterile" suture. It is my opinion that the inventors had reduced

the claimed invention to practice because the inventors had constructed and tested the claimed suture and knew that it would work as a suture for its intended purpose.

40. I also disagree with Arthrex that sterilization was needed to reduce the claimed invention to practice because sterilization of medical devices including sutures were known processes that date well before the inventors work in 1988. The typical sterilization processes are gamma sterilization and ethylene oxide. Notably, the 446 Patent refers to both types of sterilization (Ex. 4 at 6:21-29). One of ordinary skill in the art would have been aware of both methods of sterilization and the parameters for sterilizing sutures and the materials claimed in the 446 patent. Further, one of ordinary skill in the art between 1988 and 1992 would have known that sterilization under normal conditions would not have had any substantial affect on braid properties, other than sterilization. Thus, there was no need for the 446 patent inventors to sterilize the sutures that they had constructed in order to show that they would work for their intended purpose and to prove the concept of their invention.

41. I further disagree with Arthrex that sterilization was needed to reduce the claimed invention to practice because typically sterilization is done for product commercialization, not proof of concept. A suture designer would generally not sterilize his work unless it was to be tested in the body, or it involved product commercialization. Sterilization is basically a commercialization step that was not needed here to prove the concept of the invention claimed in the 446 patent. Requiring the inventor to sterilize the braided suture constructs would basically require him to make a commercial product and sterilize it in its packaging because typically sutures are sterilized in the packaging. In reality, suture designers do not sterilize suture designs to prove the concept unless the designs have something particular to do with sterilization. Here, the focus was on suture properties, and biological testing was not needed.

42. My opinion is supported by Mr. Grafton's deposition testimony concerning the development of the FiberWire product. Mr. Grafton testified that, after Arthrex tested the prototype suture braid of UHMW PE and PET, Arthrex believed it would work as a suture (Ex. 9 at 57:15-18). Although Mr. Grafton was not sure whether the sutures he tested were sterile or nonsterile (and I know of nothing indicating they were sterile), Mr. Grafton testified that sterilization would not be necessary at this stage of development, because it was only the mechanical features of the suture being tested, not the biological features (*id*. at 60:11-23). Thus, Mr. Grafton's testimony supports my opinion that sterilization is typically not needed to prove the mechanical properties of a braided suture.

43. Arthrex's argument is contradicted by Arthrex's and Pearsall's own practices. I understand that Arthrex tested unsterile sutures when it tested coated and uncoated samples to show that FiberWire's coating has an effect on FiberWire's lubricity (*id*. at 149:1-152:8). Arthrex's engineer who coordinated that testing was aware of the known sterilization techniques (*id*. at 97:5-15). He must not have thought that sterilization could have a "substantial effect" on the braid properties because otherwise he would have tested sterile sutures. If sterilization could have a "substantial effect" on the braid properties, then this casts doubt on the reliability of Arthrex's test results. Also, Pearsalls issued certificates of conformity on the braids that they made for Arthrex's FiberWire that describe certain suture properties such as knot strength. Arthrex has submitted these documents to the FDA. But Pearsalls does not sterilize sutures.

IV. Description of Polyethylene In the 446 Patent

44. It is my opinion that the 446 Patent discloses UHMW PE to one of ordinary skill in the art at the time the application for the 446 Patent was filed. The 446 Patent specifically claims "PE." Further, the 446 Patent expressly describes "polyethylene (PE)" (Ex. 4 at 4:27-30). One of skill in the art would have known that "PE" means "polyethylene" and means all polymers made

from ethylene. PE is the generic name for all types of PE, including UHMW PE. In 1987, the Encyclopedia of Polymer Science and Engineering 2nd edition volume 10 recognized polyethylene as the "common (source-based)" name for all polymers made from ethylene (Ex. 10). Further, the IUPAC officially recognized that PE is the accepted abbreviation for all types of PE (Ex. 11). Thus, one of skill in the art would have known that "PE" or "polyethylene" as used in the 446 Patent means all polymers from ethylene including UHMW PE.

45. The 446 Patent's description of PE is consistent with all types of PE. The 446 Patent states that in a preferred embodiment the first set of yarns act as lubricating yarns (Ex. 4 at 4:11-12). PE including UHMW PE is a lubricious yarn (Ex. 9 at 52:24-53:1). Cohan shows that one of skill in the art would have known that UHMW PE is a lubricious material because the UHMW PE used in the Cohan article slipped and required complex knot configurations in order to evaluate the material's knot hold strength. Also, the 446 Patent states that the first set of yarns may be derived from "non-absorbable polymers." PE including UHMW PE is a non-absorbable polymer. The 446 Patent also describes the first set of yarns as being made from fiber forming materials (Ex. 4 at 4:30-32). PE including UHMW PE is a fiber forming material. Therefore, the 446 Patent's description of PE is consistent with the meaning of PE and does not exclude UHMW PE.

46. My opinion that "PE" as used in the 446 Patent includes UHMW PE is supported by Arthrex's use of the term "polyethylene." I note that Arthrex described the UHMW PE used in FiberWire and other sutures as "polyethylene" without specifically calling out that it is UHMW PE (Ex. 12 at ARM002188-89; Ex. 13 at DMI Ex. 343). Also, I note that Cohan refers to ultrastrong polyethylene in the first instance but thereafter Cohan uses the terms ultrastrong polyethylene and polyethylene interchangeably to describe the suture materials. Further, my

opinion that one of skill in the art would understand PE to include UHMW PE is confirmed by the DSM brochure. The brochure teaches that "polyethylene" properties cover the range from 1 N/tex specific strength and 25 N/tex specific modulus to 3.5 N/tex specific strength and 150 N/tex specific modulus. It also notes that Dyneema SK60 falls within this range at 2.7 N/tex and 90 N/tex. Thus, the DSM brochure refers to UHMW PE as polyethylene, and those skilled in the art do in fact refer to UHMW PE as polyethylene, just as the inventors did in the 446 Patent.

47. My opinion is further supported by the prosecution history of the 446 patent. The Burgess reference discloses high molecular weight polythene (Ex. 14 DMI000123 at line 13-14). During the prosecution history, Mr. Goodwin referred to the high molecular weight polythene disclosed in Burgess generically as "polythene," which is the English term for polyethylene (Ex. 15 at DMI000064). Likewise, the Examiner twice referred to the high molecular weight polythene disclosed in Burgess generically as "polyethylene" (*id*. at DMI000601). Notably, both the Examiner and the applicants referred to high molecular weight polythene by its generic or common, source-based name.

48. PE includes UHMW PE to one of ordinary skill even if UHMW PE is not specifically named. Anything to the contrary does not make sense. It would assume that the well-accepted definition of PE is wrong and excludes UHMW PE. I know of no change in the well-accepted scientific naming conventions. While some authors may specifically refer to UHMW PE, my experience is that they do so when they want to emphasize the characteristics of UHMW PE as compared to PE. Here, the inventors of the 446 Patent had no reason to specifically refer to UHMW PE. PE was referred to as being lubricous. UHMW PE is lubricous. Therefore, there was no particular reason for the inventors to recite both PE and UHMW PE. Notably, the inventors

referred to other materials such as nylon, aramid, PET, PTFE, PETFE, FEP, and PP generically as well. Therefore, the term PE was not treated any differently than the other materials.

49. I understand that Arthrex incorrectly alleges that a "braid made solely of" the first set of yarns (e.g., PTFE, FEP, PFA, PVDF, PETFE, and PE) is described in the 446 Patent as "'highly pliable'" and the first set of yarns are described in the 446 Patent as "relatively weak" (Arthrex Br. at 11-12). I disagree with both assertions. First, I disagree that the 446 Patent describes the first set of yarns being "weak." The 446 Patent never describes the first fiber-forming yarns as "weak." Instead, the 446 Patent, in one embodiment, describes the first set of yarns as lubricating yarns to "improve the overall pliability or compliance and surface lubricity of the heterogeneous braid" (Ex. 4 at 4:12-14). Notably, in the background of the 446 patent it describes a "highly pliable braid" made from "highly lubricous polymers" in a "traditional manner" as being "relatively weak and unusable" in most cases (*id*. at 2:22-25). This sentence states that:

> "[i]f fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable"

(*id*.). But this is not a description of the highly lubricous material as "weak." Rather, it is a description of a certain braid – a highly pliable braid of just highly lubricous material -- as being weak, which is what one of ordinary skill would expect, because the material will likely slip (Ex. 16). But this sentence refers to braids of "highly lubricous polymers" and does not state that all permutations of the first set of yarns are all necessarily the "highly lubricous polymers" identified in the background. Further, this sentence states that "highly pliable braids can be prepared," but that does not mean that all braids made from the materials are highly pliable because they can have different stiffness characteristics or be heat treated or processed in different ways to make the braids less pliable. Also, the 446 patent says that "in most cases," not

all cases, these braids will be relatively weak. Finally, this sentence only refers to some braids as being weak, not the braided materials as being weak, as Arthrex incorrectly suggests. Thus, contrary to Arthrex's suggestion the 446 patent does not say that all braids made from all of the first fiber forming materials are all necessarily highly pliable or that the materials used to make the braids are "weak." I understand that Mr. Grafton constructed a braid of UHMW PE and had this very problem (Ex. 9 at 51:15-52:20).

50. Arthrex's assertion appears to be based on a misunderstanding of the invention described in the 446 Patent. He appears to equate lubricity with weakness and reads the 446 Patent, as describing braiding a weak yarn with a strong yarn. But this is incorrect. The 446 Patent teaches, among other things, that a lubricious yarn can be braided with another yarn of different properties (e.g., different lubricity, strength) to yield a braid that benefits from the lubricity of the first material and the strength of the second material. One of skill in the art, reading the 446 Patent, would understand that a braid of UHMW PE and PET would benefit from the lubricity of the UHMWPE and the strength of the PET. Arthrex appears to assume that because in some embodiments the 446 Patent describes the first set of yarns as being for lubricity and the second set of yarns being for adding strength, that the first set of yarns must be weak. That is not stated in the 446 Patent. Nor would one of skill in the art read "weakness" into the 446 Patent. For similar reasons, column 2, lines 26-28, of the 446 Patent do not teach that there is a necessarily a tradeoff in which the first set of yarns will somewhat weaken the braid because the increases in pliability from the first set of yarns will outweigh the loss of strength as Arthrex suggests (Arthrex Br. at 11).

51. Arthrex also cites to column 2, lines 31-37 for the proposition that the first set of yarns must be weak. But again this sentence does not state that the first–fiber forming materials will

detract from strength. Rather, it states that it would be desirable for the dissimilar materials (i.e., both the first and second yarns, not just the first yarns) to contribute significantly to enhanced pliability without appreciably sacrificing physical properties. Notably, the sentence only states that it would be desirable not to appreciably sacrifice physical properties, which means that they could be increased or decreased, not that they have to be somewhat weaken as Arthrex suggests. Further, to limit the 446 Patent to this specific desire would be inconsistent with the 446 Patent because it describes the properties much broader than just this one desire (Ex. 4 at 2:49-66).

52. Arthrex also cites to column 8, lines 19-49, for this alleged weakening proposition, but this is to a preferred embodiment of PTFE and PET yarns. This is not a discussion of all embodiments. Thus, it is improper to suggest that the specific embodiments of PTFE, which is known to be relatively weak yarn, would behave the same as other strong yarns such as PE, PP, and PVDF variants.

53. I also disagree with Arthrex's assertion that UHMW PE is not "weak." Although Arthrex refers to yarns as being "weak," it does not describe in what sense they are weak. Thus, I am not sure what Arthrex means by "weak." But, I note that Cohan described the tendency of monofilament UHMW PE to slip and the need for more complex knots when tying UHMW PE. In that sense, UHMW PE could be considered weak. I note that Arthrex made similar statements when applying for its own patent (Ex. 17 at 1:13-20). Arthrex reported in its 234 patent that UHMW PE "does not have acceptable knot tie down characteristics for use in surgical applications" (*id*. at 1:20-21). Thus, with respect to knot hold, knot tie, and knot security UHMW PE may be considered "weak."

54. Arthrex argues that the 446 patent's description of certain braids as being weak, as meaning that a braid material is "weak." But describing a braid as weak is not the same as

describing a material as weak. For example, the 446 patent describes a homogeneous *braid* of a highly lubricious material as being relatively weak, not that the first fiber-forming materials are weak (Ex. 4 at 2:23-29). This is not the same as the individual yarn being weak. Mr. Grafton confirmed this with his experiences during the development of the FiberWire product. I understand that Mr. Grafton had tried making a suture form UHMW PE but failed because the UHMW PE was too lubricious (Ex. 9 at 51:15-52:20). After he was unsuccessful with making a suture from just UHMW PE, Mr. Grafton thought of the idea of braiding UHMW PE yarns with PET yarns in direct intertwining contact (*id*. at 53:8-11). When he explained his idea to Dr. Burkhart, who I understand is a surgeon, Dr. Burkhart described the idea as “killer” (*id*. at 54:6-14).

55. I have reviewed Dr. Brookstein's report concerning the description of the first fiber forming materials and his response to Arthrex’s statements that the 446 Patent describes the first fiber forming materials as "weak." Assuming that he means, "weak" in tensile strength, I agree with Dr. Brookstein that the 446 patent does not describe the first fiber-forming materials as "weak." I have reviewed Exs. J, K, L, M, and N to Dr. Brookstein's report and agree that at least some of the first fiber-forming materials, including at least some PE, PP, PVDF (polyvinylidene fluoride) materials, are not "weak" in tension. This supports my opinion that the first fiber-forming materials are not described as "weak." Therefore, because at least some of the first fiber-forming materials are not "weak" in tension, one of skill in the art between 1988 and 1992 would not have understood the 446 Patent to disclose the first fiber-forming materials as being a group of "weak" materials. Accordingly, one of skill in the art between 1988 and 1992 would have understood the 446 patent to disclose UHMW PE by its reference to the generic name "PE."

56. Further, I was responsible for the extrusion, drawing and heat-setting of polypropylene fibers for sutures and know that polypropylene fibers are not considered "weak" fibers. While I directed suture development at U.S. Surgical we developed, manufactured and sold SURGIPRO 100% polypropylene monofilament sutures. From my own experience, 100% polypropylene monofilament sutures are not considered weak.

57. My opinion that one of ordinary skill in the art would understand PE to include UHMWPE is further supported by Arthrex's FiberWire Instructions for Use. Arthrex specifically refers to FiberWire's UHMW PE as "polyethylene" in its FiberWire instructions for use (Arthrex Br. at Ex. 14). Thus, as Arthrex's instructions for use show, those in the suture field refer to UHMWPE generically as "polyethylene."

58. It is my opinion that UHMW PE, like all PE, is lubricous. I understand that Mr. Grafton agrees (Ex. 9 at 52:24-53:1) because UHMW PE is lubricious, it is my opinion that a braid of UHMW PE would have low internal and external frictional properties that would contribute positively towards handling properties, such as tactile feel and tissue passage.

59. The Burgess reference discloses a fishing line that should have a “braided construction” (Ex. 14 at 1:9). Burgess discloses that some filaments are of “high tensile polythene thread” and other filaments are “polyester and/or nylon” (*id*. at 1:10-11). But Burgess does not disclose what kind of “braided construction” he envisioned, how to construct the braid which he references, nor how to use the materials in the “braided construction” he references. For example, Burgess does not disclose whether the polythene thread should be in the core, whether it should be in the sheath alone, or in the sheath with another material. Nor does Burgess disclose whether the polyester and/or nylon alone should be in the core, whether it should be in the sheath alone, or in

the sheath with another material. At no point does Burgess state that the polythene can be in a sheath with another material such as nylon or polyester.

60. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

4/1/06

Date

Dr. Matthew Hermes

HERMES DECLARATION
EXHIBIT 1

ksu upclose
Kennesaw State University
EXCEEDING EXPECTATIONS

Curriculum Vitae

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Profile:

Dr. Hermes is a scientist, inventor, biographer, educator and public servant with more than 40 years professional experience. At his best he evaluates patterns of relationships - whether personal, cultural or technical - and synthesizes novel and practical solutions to real-world problems. In addition to serving on the Steamboat Springs, CO Board of Education, he currently:

- writes and publishes new systems of chemical education for university students,
- consults on the processes affecting public education boards,
- writes and initiates business plans for startup enterprises and
- collects and preserves documents detailing 19th century western exploration and mapping.

Recent Accomplishments, 1986-2000:

- **As Corporate Research Scientist, 1986-1994, directed research and development leading to introduction of 1,000+ suture products for United States Surgical Corp. Conceptualized, created and protyped products. Designed, built and operated manufacturing. Holds 29 US Patents**
- Discovered and patented practical methods for stabilizing moisture sensitive fibers against hydrolysis. Invention reduced time to market introduction by five years.
- **Envisioned and patented non-protein polymer systems incorporating unique features of predetermined length, composition and sequence. These distinctive properties in proteins drive all living systems.**
- As Adjunct Professor of Chemistry at Wyoming, developed synthetic methods for structural assembly of polyesters with predetermined sequence. Monodisperse oligomers show protein-like configuration.
- **Completed biography "Enough for One Lifetime, Wallace Carothers, Inventor of Nylon", published by the American Chemical Society March 1996.**

- As Contract Consultant to Colorado Advanced Technology Institute, taught Applied Telecommunications to twelve rural Colorado governments and entities. Actively developing and maintaining four World-Wide-Web Internet sites with over 150 documents. AeRie presentation of Rural telecommunications chosen "Pick of the Week", May 1, 1995 by NCSA. Developed and managed web communications for Dept. of Commerce TIIAP GIS development grant.
- **Marketing resort lodging through Internet connectivity, developing electronic marketing data and plans, 1995-1998. Commercial telemarketeing resulted in $2.25M new business for Yampa Valley, Colorado.**
- Currently, President, F. V. Hayden Institute, educational and scientific Institute distributing applied telecommunications to the rural west. Vice-President, CyberCastles, Inc., telecommunciations marketing in the Rural West.
- **Project Director, ChemCases.Com, National Science Foundation-funded University General Chemistry curriculum development project. Written and published two ChemCases. Currently Adjunct Professor of Chemistry, Kennesaw State University, Kennesaw, GA.**
- Elected to Steamboat Springs, Colorado RE-2 Board of Education, 1997.
- **Completed digitizing the 1881 "Atlas of Colorado". Produced CDROM of maps and western art as educational and recreactional resource for the US Forest Service.**
- Consultant in public board of education "policy governance" with Aspen Group International.

Recent United States Patents:

4,744,365(1988) Compositions for Absorbable Surgical Devices
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- Wallace Carothers, Inventor of Nylon, Presentation to the Wyoming Section of the American Chemical Society, April 27, 1993.
- Polyesters of Predetermined Sequence, with Dr. Bin Huang, Journal of Polymer Science, Vol. 33, p.1419(1995).

Career Profile:

Education:

- B. S. Chemistry, St. John's University, Brooklyn, NY, 1955.
- Ph. D., Chemistry, University of Maryland, 1959.
- M. A., Liberal Studies, Wesleyan University, 1992.

Employment History:

- Research Chemist, Supervisor, E. I. DuPont, 1959-79.
- Research Director, Virginia Chemicals, Celanese Co., 1979-83.
- Corporate Research Scientist, U. S. Surgical Corp., 1983-94.
- Adjunct Professor, University of Wyoming, 1992-1994
- Consultant, Colorado Advanced Technology Institute, 1995-7

- President, F. V. Hayden Institute, 1996-present
- Adjunct Professor, Kennesaw State University, 1997-present

Early Accomplishments, 1955-1983:

- With Prof. William Bailey at Maryland, produced monomers and polymers demonstrating polymerization through Diels-Alder polymerization.
- At DuPont Central Research, discovered the chemistry of the treacherously explosive cyanogen azide. Developed safe handling methods and described mechanism of ring-chain tautomerisms and skeletal rearrangements.
- At DuPont solved the thirty-year problem of moisture degradation of abrasion resistant coatings for transparent acrylic sheet.
- At Virginia Chemicals, unraveled mystery of large industrial explosion and rationilized thermochemistry of the inorganic paper chemical, sodium hydrosulfite.

Early Publications:

W. J. Bailey, M. E. Hermes et al., Journal of Organic Chemistry, 27,1975(1962)
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Personal

Single, Excellent Health.
Director, Steamboat Springs RE-2 School Board; Secretary, Steamboat Springs Education Fund Board; Steamboat Springs Kiwanis; American Chemical Society.

04/7/00

HERMES DECLARATION
EXHIBIT 2

US005318575A

United States Patent [19]

Chesterfield et al.

[11] Patent Number: 5,318,575

[45] Date of Patent: Jun. 7, 1994

[54] **METHOD OF USING A SURGICAL REPAIR SUTURE PRODUCT**

[75] Inventors: **Michael P. Chesterfield**, Norwalk; **Ilya Koyfman**, Orange, both of Conn.

[73] Assignee: **United States Surgical Corporation**, Norwalk, Conn.

[21] Appl. No.: **829,423**

[22] Filed: **Feb. 3, 1992**

[51] **Int. Cl.**[5] **A61B 17/00**

[52] **U.S. Cl.** **606/151**; 606/228; 606/231; 128/898; 623/13

[58] **Field of Search** 606/228, 231, 151; 623/13; 128/898

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Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—J. A. Schmidt

[57] **ABSTRACT**

Textile surgical articles are disclosed which are constructed in whole or in part from high tenacity low elongation fibers such as ultra-high molecular weight extended chain polyethylene high tenacity fibers. The products may be braided, woven or knitted, such as braided tapes, hollow braids and spiroid braids. The high tenacity low elongation fibers provide structures having greatly increased strength and decreased elongation, a combination of properties which is uniquely applicable and superior for repairing body tissue. The products may be plasma treated to reduce slip.

12 Claims, 2 Drawing Sheets

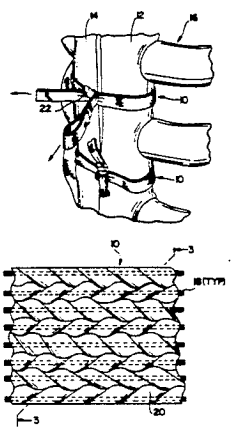

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FIG. 1

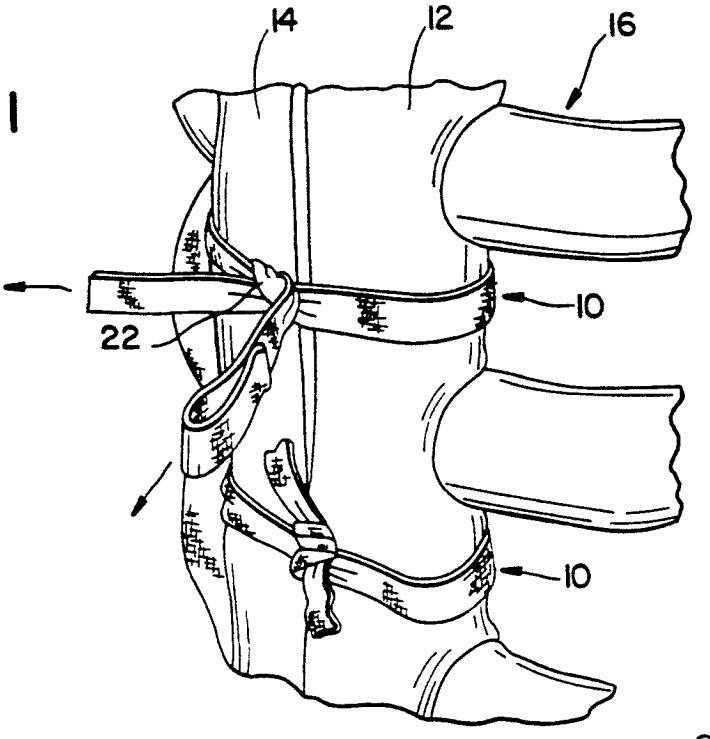

FIG. 2

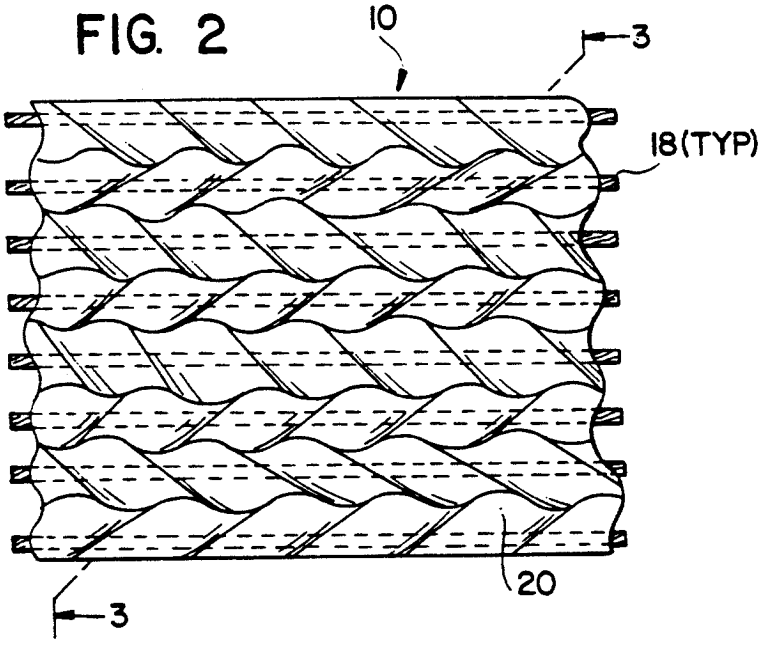

FIG. 3

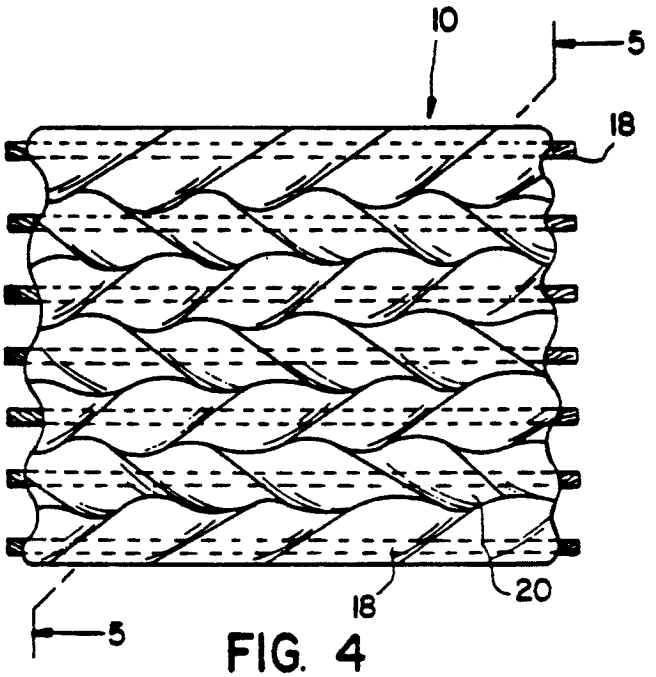

FIG. 4

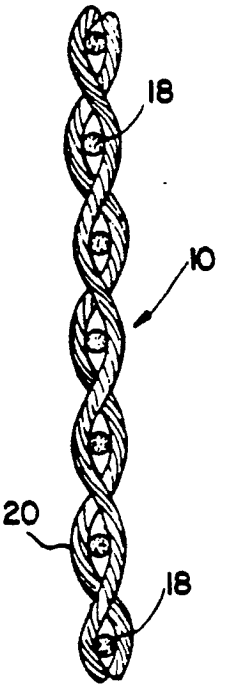

FIG. 5

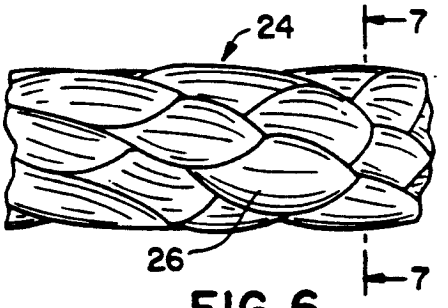

FIG. 6

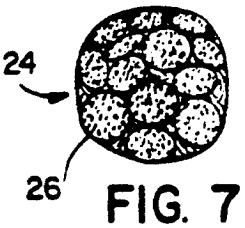

FIG. 7

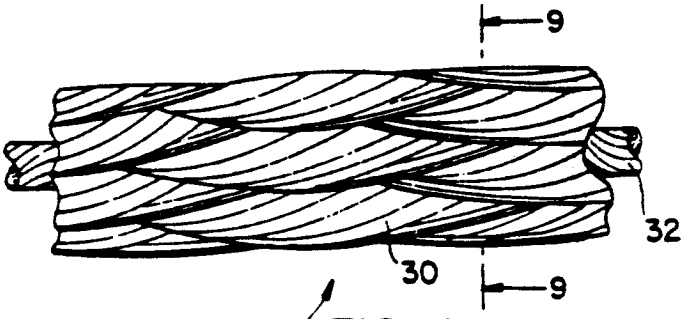

FIG. 8

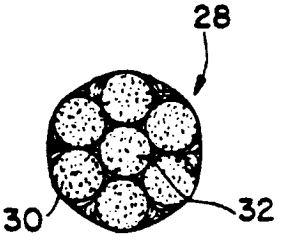

FIG. 9

METHOD OF USING A SURGICAL REPAIR SUTURE PRODUCT

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to suture products for surgical repair of body tissue. In particular, the invention is directed to reinforced surgical repair products for repairing the human sternum after surgery.

2. Background of the Prior Art

Presently there are many known products for repairing human body tissue in areas where a repair may be required either as a result of an injury or during or after surgery. In particular, it is well known to utilize suture products in the form of elongated strands to repair human body tissue as well as utilizing two-part fasteners or metal staples for attaching body tissue after portions have been removed during surgery.

For example, sutures intended for repairing soft body tissue are usually constructed of a plurality of filaments and applied to the tissue with any number of surgical needles. More recently, a certain amount of emphasis as been placed upon repairing surgical bone utilizing an elongated surgical product either in the form of a flat band or in the form of a strand having the construction similar to a suture by simply utilizing a needle to penetrate the bone to apply the repair product to the bone in a manner which physically retains the separated bone portions together to promote permanent healing. One such example is disclosed in U.S. Pat. No. 4,535,764 to Ebert which relates to a surgical bone tie having a needle connected to one end of a band such that the band may be looped and arranged to be appropriately looped around the bone portions requiring repair.

U.S. Pat. No. 4,813,416 relates to a band assembly and method for sternum closing with which the sternum halves are brought to abutting closure utilizing a band having a needle at one end to facilitate looping the band in position to retain the sternum portions in adjacent butting contacting relation.

Numerous other products have been used to retain bone portions together to promote healing while numerous suture products have been used to retain soft tissue to retain healing.

While many attempts have been made to provide such products little emphasis has been applied to the physical strength characteristics of the components which form the actual suture or band product in order to provide the surgeon with precision control on the product. Moreover, control is required on the tissue to which the product is applied in a manner which will promote healing of the tissue, yet will not cause unnecessary cutting of the tissue when force is applied to the product and the force is in turn applied to the tissue.

A particularly desirable product for accomplishing these goals would preferably display substantial strength without significant elongation to facilitate retaining the tissue portions together. In the case of attaching separate bone portions of the sternum together after open heart surgery for example, it has been necessary to utilize metal wire filaments by looping the wire filaments around the sternum portions and actually twisting the filament ends together to form an attachment. The metal wire displayed sufficient strength to retain the bone portions together without elongation. However, the wire represented a relatively sharp non-absorbable foreign body which remains embedded within the body tissue and thus presents a potential source of infection or other complications as a result of its presence within the body. Moreover, the relatively sharp characteristics of the wire present a danger of cutting into the bone during the application to the sternum. The sharp wire also presents a hazard to the surgeon and operating room personnel in that the wire may penetrate surgical gloves and cut the surgeon or attendant personnel, thereby creating a potential site for transmission of disease.

While utilization of wire sutures has been used and accepted during open heart surgery there remains room for improvement in the products used for strapping the split sternum portions together. Desirably, it would be best to provide a known metallic product which not only provides the strength to elongation characteristics of the metal sutures but which may be utilized to form a tying product for soft as well as hard tissue, in a manner which will minimize the dangers of cutting of the tissue in the surrounding areas. The present invention is directed to such a product.

SUMMARY OF THE INVENTION

In accordance with the present invention, textile surgical articles are disclosed which are made in whole or in part from high tenacity low elongation fibers such as ultra high molecular weight extended chain polyethylene high tenacity fibers. One such fiber is Spectra yarn from Allied Signal Corp. The products may be braided, woven or knitted, although braided tape, hollow braids and spiroid braids are preferred. The high tenacity low elongation fibers provide structures having greatly increased strength and decreased elongation.

In one embodiment, braided tapes are made from Spectra yarn. In an alternative embodiment braided tapes are made with Spectra runners and bioabsorbable, Dacron polyester and/or nylon fill yarns.

Further alternative embodiments include tubular braided structures having a core made in whole or in part from high tenacity low elongation fibers or spiroid braided structures made in whole or in part from high tenacity low elongation fibers.

In a preferred method of the invention, a braided tape reinforced with ultra-high molecular weight high tenacity fibers is used to join a divided sternum by tying, or other appropriate means. The tape has a very high strength, preferably equal to or greater than 35 kg. straight pull and more preferably greater than about 50 kg. straight pull, and low elongation at break, preferably below about 20%, more preferably below about 10 to 15%, and most preferably below about 5%.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described hereinbelow wherein:

FIG. 1 is a perspective view of a portion of a split human sternum illustrating one application of the present invention for retaining the split portions together to promote healing;

FIG. 2 is an enlarged view of the suture product shown in FIG. 1 illustrating one embodiment wherein the elongated product is a flat braided member and contains at least eight reinforcing filaments extending along the length;

FIG. 3 is a cross-sectional view taken along lines 3—3 of FIG. 2.;

FIG. 4 is an enlarged view of an alternative embodiment of the suture repair product of FIG. 2 wherein the elongated braided product contains at least seven reinforcing filaments extending along the length;

FIG. 5 is a cross-sectional view taken along lines 5—5 of FIG. 4;

FIG. 6 is a view of an alternative embodiment of the suture repair product wherein the elongated member is a spiroid braided member having a generally circular cross-section containing at least one elongated reinforcing member;

FIG. 7 is a cross-sectional view taken along lines 7—7 of FIG. 6;

FIG. 8 is a view of another alternative embodiment of the suture repair product wherein the elongated product is a hollow braided member having a generally circular cross-section and contains at least one elongated reinforcing member extending centrally thereof along the length; and

FIG. 9 is a cross-sectional view taken along lines 9—9 of FIG. 8.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to FIG. 1 there is illustrated a sternum closure ribbon 10 constructed according to the present invention and positioned to retain portions 12,14 of a human sternum 16 together. The band 10 is preferably a braided product as shown in FIGS. 2 and 4 having a plurality of elongated filamentary reinforcing members of ultra high molecular weight polyethylene fibers. The fibers may be plasma treated to reduce slip characteristics of the yarn, if desired. In particular, such fibers as extended chain polyethylene high tenacity fibers (ECPE) marketed under the trademark SPECTRA ® by Allied-Signal Technologies, Petersburg, Va. 23804 are preferred as reinforcing members provided in the product of the present invention. SPECTRA 1000 yarn is suitable. These extended chain fibers exhibit a molecular weight generally between about 1 million to about 5 million but also may be as low as 500,000. They exhibit a very substantial degree of crystalline orientation (95–99%) and crystalline content (60–85%). As a result the fibers exhibit strengths from about 375 kpsi (thousands of pounds per square inch) to about 560 kpsi and tensile moduli of from about 15 msi (millions of pounds per square inch) to about 30 msi. The significant strength and stability of these fibers are caused by the high degree of molecular orientation. Moreover, since the fibers can be provided as multifilament or monofilament fibers which can be braided, woven, knitted or otherwise processed to form a textile product it will be readily appreciated that any number of reinforced textile products may be provided similar to the band 10 shown in the drawings, but with numerous alternative applications as will be described hereinbelow.

Referring now to FIG. 2, the band 10 shown in FIG. 1 is shown in greater detail as an elongated flat braided textile product having a plurality of high molecular weight fibers 18 extending along the length of the band.

The elongated fibers 18 are preferably made of ECPE marketed under the SPECTRA ® trademark and are surrounded by braided fibers 20 which may be of the bioabsorbable type. For example, fibers 20 may be made of any suitable bioabsorbable polymeric material such as polymers or copolymers of glycolide, lactide, p-dioxanone, polyester, polyamino acids and the like as disclosed in U.S. Pat. Nos. 2,668,162; 3,297,033; 3,636,956; 3,736,646; and 3,839,297. The number of reinforcing filaments 18 included in the braided band 10 shown in FIG. 2 is optional as is the specific construction of the band. For example, as seen in FIG. 4, there is an example of an alternative braided band construction having seven reinforcing filaments 18 of high molecular weight, high strength fibers of the type shown in FIG. 2. Furthermore, as seen in FIG. 7, there is an alternative elongated embodiment of spiroid braided construction of generally circular cross-section and comprised of one or more elongated filaments 26 of high molecular weight, high strength, with the remainder of the braid being of bioabsorbable filamentary materials to form a braided rope-like construction of generally circular cross-sectional configuration as shown in FIG. 7. Alternatively the braided product 22 may be constructed entirely of such high molecular weight, high strength, elongated filaments 24. Braid constructions having a circular cross-section are described in U.S. Pat. Nos. 3,565,077 and 5,019,093. Any number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated, depending upon the intended application.

In FIGS. 8 and 9 there is shown a hollow braid construction 28 having a sheath constructed of bio-absorbable yarns 30 and having a core 32 of high molecular weight, high strength filament. Any number of alternative combinations of 0 to 100% absorbable filamentary or otherwise,. and/or non-absorbable yarns and high strength filaments are contemplated depending upon the intended application.

It will be appreciated that in addition to the examples which follow hereinbelow, numerous alternative textile constructions may be incorporated into the present invention to form a reinforced band for attaching body tissue such as a soft tissue or bone tissue without suffering from the disadvantages from presently known materials. For example, it is conceivable within the scope of the present invention to provide a woven structure containing a plurality of elongated high strength filaments 18 in the warp direction wherein the filler yarns are of a suitable bioabsorbable material such as polymers or copolymers of glycolide, lactide, p-dioxanone, polyester, polyamino acids and the like, or with fill yarns of a nonabsorbable material such as Dacron polyester or nylon. Likewise, knitted structures may be strengthened by reinforcement with high tenacity fibers. It will be appreciated that in each of the embodiments discussed herein the strength characteristics of the high tenacity, low elongation fibers 18 will provide the substantial force carrying capability to the elongate product while the fibers 20 surrounding the high strength filaments will provide the necessary structural support to the main fibers for forming the product. The surrounding fibers will also define the "hand" or "feel" of the band.

Accordingly, it is possible in one application to position the reinforced structure 10 about the split portions 13,14 of the human sternum 16 as shown in FIG. 1 whereby substantial force may be applied to the band by tying the band either by a knot 22 shown in FIG. 1, or by other techniques whereby significant force may be applied and retained to promote natural healing of the sternum portions 12,14, e.g. mechanical connecting devices such as buckles, etc. See, for example, U.S. Pat. No. 4,813,416. It has been found that such a band has a strength to elongation ratio comparable to stainless

steel. The strength and load carrying capability of the elongated filaments **18** is sufficient to transmit substantial force to the sternum with minimum elongation occurring to the fibers thereby permitting the sternum portions to undergo a natural healing process. Furthermore, in addition to the textile processes of braiding and weaving it should be noted that alternative textile processes may be utilized including knitting techniques, provided that the final product contains a plurality of elongated high strength filaments **18,22** extending along at least the length of the product in the force-carrying direction to maintain the tissue portions together.

The braided product also may be made on a so-called spiroid braider by a method whereby a plurality of filament dispensers are moved in the same direction to different positions around a closed loop. In addition, the braid product may be produced by a conventional braiding process by directing a plurality of yarn dispensers along in equal and opposite undulating paths while directing the filaments or filler fibers toward a common braiding zone. In either process the final braided product will be manufactured to include a plurality of high strength, high molecular weight, high tenacity filaments as disclosed hereinabove, either as a component of the product, e.g. a core, or as the sole material used to construct the product. In addition, the yarn and/or product may be plasma treated depending upon the particular needs or intended application so as to reduce the perceived "slipperiness" of the product as desired.

For example, in any of the braided products disclosed herein the portions of the yarns may be of such high molecular weight, high tenacity filaments while the remaining portions are of absorbable or non-absorbable fibers or filaments. Further, the yarns may also be entirely of such high molecular weight, high tenacity filaments. For such products containing a core, the core may be as noted above, in combination with various types of fibers and/or filaments, absorbable or non-absorbable as described herein.

The final product could be provided with a surgical needle at one or both ends to facilitate insertion of the product into the body tissue whether the body tissue be soft skin tissue or hard bone tissue, or the needles may be utilized to facilitate looping the product into and out of spaces formed between the component members of the body such as the components forming the human sternum. Alternatively, the product could be provided with a needle at each end to facilitate ease of application to the body portions. In either event, the strength and the load carrying filaments **18** and the minimal elongation to strength percentage renders such filaments ideal for incorporation into a final product wherein body portions can be retained together to promote healing. In particular, the formation of a surgical suture repair product utilizing textile processes in combination with bioabsorbable filaments renders the incorporation of high tenacity, high strength, high molecular weight filaments **18** as an ideal combination to form a surgical suture repair product.

The following examples are provided for flat tapes and braids which can be utilized to tie two half portions of a human sternum to promote healing. In the examples which follow, all tapes or braids use Dacron polyester yarn. Braiding of the tapes or braids with Dacron yarns are noted for exemplary purposes only and such yarns may be appropriately substituted with any other suitable bioabsorbable or nonabsorbable yarns, as desired or appropriate for a particular construction. Of course, substitution of different yarns may require variations to the structure as required to accommodate changes in density and/or fiber denier. The fibers may be twisted or air entangled periodically to create a false twist.

EXAMPLE 1

A braided tape of Spectra 1000 high tenacity polyethylene multifilament fibers (60 filaments, 215 denier) was made on a 15 carrier flat tape braider with 7 parallel runners. This structure is shown in FIGS. **4** and **5**. Tests showed the following properties.

Denier =	10,585
Tape Thickness =	0.66 mm
Tape Width =	3.91 mm
Knot pull =	47.5 kg
Straight pull =	66.5 kg
Pick count =	20 crossovers per inch

The tape of this example was made with air entangled rather than twisted yarn. It is contemplated that the yarn could instead be twisted prior to braiding, with all or some of the yarn twisted in either the "s" or "z" directions. Twisted yarn should increase strength and decrease slipperiness of the tape.

EXAMPLE 2

A braided tape having multifilament Spectra 1000 runners (60 filaments, 215 denier) and Dacron fill yarns was made on a 17 carrier braider with 8 parallel runners. This structure is shown in FIGS. **2** and **3**. The Dacron fill yarns were made with three plies of air entangled 100 denier, 54 filament Dacron type 55 yarn. The properties of the tape were measured as follows:

Denier =	7,551
Tape Thickness =	0.34 mm
Tape Width =	3.14 mm
Knot pull =	36.5 kg
Straight pull =	53.6 kg
Elongation at break =	3.4%
Pick count =	26 crossovers per inch

EXAMPLE 3

A braided tape is made with Spectra 1000 runners (60 filaments, 215 denier) and nylon fill yarn. The nylon fill yarn is made from three plies of 100 denier, 34 filament type 385 Dupont bright air entangled nylon yarns. The tape may be made to the desired width, thickness and pick count on any appropriate braider, such as a 15 carrier braider with 7 runners or a 17 carrier braider with 8 runners or a 21 carrier braider with 10 runners.

EXAMPLE 4

A braided tape is made with Spectra 1000 runners (60 filaments, 215 denier) and a bioabsorbable fill yarn such as a yarn made from a copolymer of glycolide and lactide. The bioabsorbable fill yarn may be twisted or air entangled and plied to a total denier of about 300 denier. the tape may be made to the desired width thickness and pick count on any appropriate braider, such as a 15 carrier braider with 7 runners or a 17 carrier braider with 8 runners or a 21 carrier braider with 10 runners.

EXAMPLE 5

A braided tape of plasma treated spectra 1000 high tenacity polyethylene multifilament fibers (60 filaments, 215 denier) was made on a 15 carrier flat tape braider with 7 parallel runners. Tests showed the following properties:

Denier =	5,338
Tape Thickness =	0.40 mm
Tape Width =	3.21 mm
Knot pull =	47.5 kg
Straight pull =	66.5 kg
Elongation at break =	8.6%
Pick count =	25 crossovers per inch

The tape of this example was made with air tangled rather than twisted yarn. It is contemplated that the yarn could instead by twisted prior to braiding, with all or some of the yarn twisted in each of the "s" or "z" directions.

The tape made from plasma treated yarn was perceptibly less slippery than the tape of Example 1, which may be desirable under some circumstances.

EXAMPLE 6

A suture of spiroid braid construction was made on a 15 carrier spiroid braider using Spectra 1000 yarn (60 filament, 215 denier). The braid is shown in FIGS. **6** and **7**. The braid had the following properties.

Denier =	3,248
Diameter =	0.832 mm
Knot pull =	32.4 kg
Straight pull =	43.0 kg
Elongation at break =	14%

Spiroid sutures may be made with twisted yarn with a variety of carriers, such as 9, 12, 20 or 25 carriers, as desired to obtain a particular configuration.

EXAMPLE 7

A suture of hollow braid construction having a Spectra 1000 core was made, and is shown in FIGS. **8** and **9**. Dacron air entangled bright polyester yarn (40 denier, 8 filament, type 55) was used on the carriers of an 8 carrier braider (4 carriers travelling in the S direction, 4 carriers travelling in the Z direction) to make a sheath surrounding a core of untwisted Spectra 1000 yarn. The properties of the suture were as follows.

Denier =	550
Diameter =	0.20 mm
Knot pull =	3.9 kg
Straight pull =	7.9 kg
Elongation at break =	3.3%

A wide variety of hollow braid constructions are contemplated. Thus, sutures having Spectra 1000 core or components can be made on braiders having 12, 16, 24, 28 or 32 carriers, and numerous yarns can be used to form a sheath surrounding the core, such as bioabsorbable yarn; Dupont Dacron polyester air entangled bright yarn (such as 100 denier, 54 filament type 55 bright yarn or 70 denier, 34 filament type 52 bright yarn); or Dupont air entangled nylon yarn (such as 40 denier, 13 filament type 335 bright yarn or 100 denier 34 filament type 385 bright yarn or 70 denier, 34 filament type 185 bright yarn or 55 denier 17 filament type 865 bright yarn, or 15 denier 7 filament type 180 bright yarn).

The core yarns may be twisted to condense the structure or plied to increase strength and denier. The sheath yarns may also be twisted, if desired.

In the foregoing examples, all physical tests were conducted at 73° F., 50% relative humidity on an Instron Corporation Model 4502 test apparatus. Knot pull tests were performed using a 6 inch gauge length with a 0.5 inch per minute crosshead speed. Straight pulls were made using a 10 inch gauge length with a 10 inch per minute crosshead speed. Yarn or tape grips were used, as appropriate.

While the foregoing description contains many specifics, it will be understood that numerous modifications may be made within the scope of the appended claims. By way of example, a wide variety of yarn substitutions may be made to arrive at various braided tape or hollow and spiroid suture configurations constructed in whole or in part from high tenacity reinforcing fibers. In addition, bioabsorbable and non-bioabsorbable yarns may be substituted as desired to achieve properties and characteristics suitable for a particular situation.

We claim:

1. A method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue in a manner to attach the portions in adjacent engaged relation to promote natural healing thereof, said flexible member being formed at least in part of first fibers of ultra-high molecular-weight high tenacity material and at least second fibers which differ from said first fibers and are formed from a non-absorbable material, said first and second fibers being braided to form said elongated member.

2. The method of claim **1** wherein the molecular weight of said fibers is within the range of from about 500,000 to about 5 million.

3. The method of claim **2** wherein said fibers comprise high tenacity extended chain polyethylene fibers.

4. The method of claim **1** wherein said elongate member has an elongation to break below about 15%.

5. The method according to claim **1** wherein said elongate member is of a flat braided construction.

6. The method according to claim **1** wherein said elongate member is of hollow braid construction.

7. The method according to claim **6** wherein said hollow braid contains a core.

8. The method according to claim **1** wherein said elongated member is of spiroid braid construction.

9. The method according to claim **8** wherein said spiroid braid has a substantially circular cross-sectional shape.

10. The method according to claim **1** wherein said elongated member has a straight pull greater than about 35 kg.

11. The method according to claim **1** wherein said second non-absorbable fibers are formed from nylon.

12. The Method according to claim **1** wherein said second non-absorbable fibers are formed from polyester.

* * * * *

HERMES DECLARATION
EXHIBIT 3

#9
Amdt A
S. Bruce
6/11/03

Docket No.: A8130.0013/P013
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
R. D. Grafton

Application No.: 09/950,598 Group Art Unit: 3731

Filed: September 13, 2001 Examiner: G. Phanijphand

For: HIGH STRENGTH SUTURE MATERIAL

AMENDMENT

Box Non-Fee Amendment
Commissioner for Patents
Washington, DC 20231

Dear Sir:

In response to the Office Action dated March 12, 2003, please cancel claim 4, amend claims 1, 3, 5-6, 8-9, and add new claim 10 in the above-identified U.S. patent application as shown in the Section marked "Amendment to the Claims".

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AMENDMENTS TO THE CLAIMS

1. (amended) A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. (original) The suture filament of claim 1, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. (currently amended) The suture filament of claim 1, wherein the polyester comprises about 40% of the braided ~~filaments~~ fibers.

4. (canceled)

5. (currently amended) The suture filament of claim 1 ~~4~~, wherein the core comprises about 30% of the filament.

6. (currently amended) The suture filament of claim 1 ~~4~~, wherein the cover comprises about 70% of the filament.

7. (original) The suture filament of claim 1, further comprising a coating disposed on the cover.

8. (currently amended) A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester, ~~and~~;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. (currently amended) A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester~~, and~~;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

10. (new) The suture filament of claim 1, wherein the polyester is non-absorbable.

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REMARKS/ARGUMENTS

Claims 1, 3, 5, 6, 8, and 9 have been amended. Claim 4 has been canceled. Claim 10 has been added. Accordingly, claims 1-3 and 5-10 presently are pending.

Claims 1 and 4-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,045,571 to Hill et al. Claims 1 and 4-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,318,575 to Chesterfield et al. Claim 7 stands rejected under 35 U.S.C. § 103 as being unpatentable over Chesterfield et al. in view of U.S. Pat. No. 4,047,533 to Perciaccante et al. Applicant respectfully traverses the prior art rejections.

The present invention as recited in amended claim 1 is a suture filament suitable for use as a suture or ligature. The suture filament includes a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester, and a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

In contrast to the present invention, Hill et al. discloses a surgical cord having a braided core. According to the disclosure of Hill et al., twisted cores are disadvantageous. Consequently, Hill et al. discloses cores formed of interlocking yarns, "as distinguished from twisted" cores. Instead of being twisted, the core yarns are "interlocked" by braiding or knitting. Thus, Hill et al. does not disclose or suggest the present invention, but rather teaches away from the present invention having a twisted core. Further, Hill et al. does not disclose suture made of ultrahigh molecular weight polyethylene. On the contrary, Hill et al. discloses polyethylene terephthalate (PET) in the molecular weight range of 30,000 to 45,000, and isotactic polypropylene homopolymer having a weight average molecular weight of from about 260,00 to about 420,000. Hill et al. does not discuss ultrahigh molecular weight polyethylene. Claim 1, and its dependent claims 2, 3 and 5-7 are submitted as being patentable over Hill et al.

Chesterfield et al. '575 discloses various surgical constructs that utilize ultrahigh molecular weight polyethylene, but does not disclose the invention recited in the claims as

presently amended. The Examiner refers to Figs. 2 and 3 and associated text from the Chesterfield et al. '575 patent, but applicant notes that these figures disclose a band 10, in contrast to the suture filament having a core and a cover as recited in claim 1 of the present application. Applicant notes further that none of the examples disclosed in the Chesterfield et al. '575 patent provides a suture having an UHMWPE core surrounded by a braided sheath or cover that includes a blend of both UHMWPE and polyester. On the contrary, the suture construction of Example 6 of Chesterfield et al. '575 has no core. The suture of Example 7 of Chesterfield et al. '575 uses a Spectra 1000 core surrounded by a hollow braided sheath made of a single type of yarn. See col. 7, line 61 to col. 8, line 5. Applicant respectfully submits that Chesterfield et al. '575 does not anticipate the present invention as recited in amended claim 1.

Claims 2 and 3 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chesterfield et al. Applicant respectfully traverses the prior art rejections.

Claims 2 and 3 of the present invention contain limitations regarding percentages of UHMWPE and polyester in the braided fibers of the suture cover. As noted above, Chesterfield et al. '575 does not disclose an example of a braided sheath that includes a blend of both UHMWPE and polyester. Consequently, it appears that the motivation for selecting a particular percentage by which the fibers are blended comes only from applicant's disclosure. Further, the Office action lacks evidence supporting the Examiner's contention regarding the knowledge in the art on varying the composition of a suture. Dependent claims 2 and 3 are submitted as being patentable over the cited references.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chesterfield in view of U.S. Pat. No. 5,720,765 to Thal. Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chesterfield et al. in view of U.S. Pat. No. 6,063,105 to Totakura. Applicant respectfully traverses the prior art rejections.

The present invention as recited in claim 8 is a suture assembly including a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh

molecular weight polyethylene and fibers of polyester, and a core formed of twisted fibers of ultrahigh molecular weight polyethylene. A suture anchor is attached to the suture. Claim 9 recites a suture assembly having suture with a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester, and a core formed of twisted fibers of ultrahigh molecular weight polyethylene. A half round, tapered needle is attached to the suture.

Chesterfield et al. '575 discloses various surgical constructs that utilize ultrahigh molecular weight polyethylene, but does not disclose the invention recited. As noted above, the Office action refers to Figs. 2 and 3 and associated text from the Chesterfield et al. '575 patent, but these figures disclose a band 10, in contrast to the suture filament having a core and a cover as recited in claims 8 and 9 of the present application. Also, none of the examples disclosed in the Chesterfield et al. '575 patent provides a suture having an UHMWPE core surrounded by a braided sheath or cover that includes a blend of both UHMWPE and polyester. On the contrary, the suture construction of Example 6 of Chesterfield et al. '575 has no core. The suture of Example 7 of Chesterfield et al. '575 uses a Spectra 1000 core surrounded by a hollow braided sheath made of a single type of yarn. See col. 7, line 61 to col. 8, line 5. Applicant respectfully submits that Chesterfield et al. '575 does not disclose the present invention as recited in claims 8 and 9.

The patents to Thal and Totakura have been cited as providing a suture anchor and a half-round, tapered needle, respectively. Neither of the patents discloses or suggests a braided suture having a blended sheath and a twisted core as recited in independent claims 8 and 9 of the present application.

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In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Dated: June 4, 2003

Respectfully submitted,

By _____
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